UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 14, 2021

MEMORANDUM

Subject: Section 18 Public Health Emergency Exemption for Grignard Pure for the States of Tennessee (TN) and Georgia (GA)
File Symbols: 21TN02 and 21GA02
DP Barcodes: 460426 and 460429; Submission Nos: 1062119 and 1062123
E-Sub #: N/A

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Nashville, TN 37220

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Formulation from the Label:

Active Ingredients	% by wt.
Triethylene Glycol	52.25 %
Other Ingredients:	47.75 %
Total	100.00 %

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I BACKGROUND

The Tennessee Department of Agriculture, Division of Consumer and Industry Services, (Pesticide Section) and Georgia Department of Agriculture (Pesticide, Feed, Seed & Fertilizer) are requesting a Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) Section 18 Public Health Emergency Exemption for the use of Grignard Pure to reduce the spread of COVID-19 by controlling SARS-CoV-2 virus in the air. According to the applicants, this action is warranted due to the urgency of the public health emergency caused by the SARS-CoV-2 virus and the impracticality of waiting for a Section 3 registration.

The product is currently unregistered.

The current submission includes the following documents to support efficacy evaluations:

- Grignard Pure EPA PowerPoint (revised)
- EPA Form 8570-4 Confidential Statement of Formula;
- Presentation to the EPA—Connecting Air Concentrations to Efficacy and Safety Values, from technical meeting on 12/9/2020
- Determine Total Concentration of Triethylene Glycol in the Air when Utilizing Grignard Pure and Determine Correlation of Air Concentration of Aerosol Monitor Measurements, dated 9/23/2020
- Grignard Pure Haze Air Density Chart, not dated

- Rutgers Office of Research and Economic Development, The Use of MS2 Phage as a Surrogate for Inactivating SARS-CoV2, dated September 4, 2020
- Boston University School of Medicine, Department of Microbiology, Use of MS2 Bacteriophage as an Infectious Virus Surrogate in SARS-CoV-2 Inactivation Studies, dated October 4, 2020
- Grignard Responses to EPA Technical Questions (#1 – 10/6/2020; #2— 11/3/2020; #3 – 11/25/2020)
- Product Specific Efficacy Data:
    - "Evaluation of Bioaerosols and Grignard's Test Substance, Study # NG15621 (identified as: Microchem_Custom Aerosol Study Report NG 15621 – A1 (3 minute – light Haze)/Amhaze Stadium Haze Machine
    - "Evaluation of Bioaerosols and Grignard's Test Substance, Study # NG15621 (identified as: Microchem_Custom Aerosol Study Report NG 15621 –A2_073120 (3 minute – light fog) /Hurricane 1800 Flex
    - "Evaluation of Bioaerosols and Grignard's Test Substance, Study # NG15621 (identified as Microchem_Custom Aerosol Study Report NG 15621 –A3_With Log Calculations (1 minute – light haze)/ Amhaze Stadium Haze Machine
    - "Evaluation of Bioaerosols and Grignard's Test Substance, Study # NG15232 (identified as Microchem_Custom Aerosol Study Report NG 15232_073120 (10 minute – moderate fog) /Hurricane 1800 Flex
    - "Evaluation of Bioaerosols and Grignard's Test Substance, Study # NG16240 (identified as Microchem_Custom Aerosol Study Report NG 16240_092520_V1 (Non Visible and Very Light Haze)/ Amhaze Stadium with remote
    - Virucidal Efficacy of a Disinfectant Applied to a Room Via a Fogging, Misting or Vaporizing Device Against Human Coronavirus
    - Virucidal Efficacy of a Disinfectant Applied to a Room Via a Fogging, Misting or Vaporizing Device Against Human Adenovirus Type 5
- Peer Reviewed Publications
    - Bourouiba, L. (2020) Turbulent Gas Clouds and Respiratory Pathogen Emissions. Potential Implications for Reducing Transmission of COVID-19, JAMA.
    - Robertson, O. (1942) The Bactericidal Action of Propylene Glycol Vapor on Microorganisms Suspended in Air. (Journal not provided)
    - US Army (1943) The Lethal Effect of Triethylene Glycol Vapor on Airborne Bacteria and Influenza. Science Vol. 97, No. 2510
    - Rosebury, T. (1946). Disinfection of Clouds of Meningopneumonitis and Psittacosis Viruses with Triethylene Glycol Vapor.
    - Wise, H. (1947) Saturation Concentrations of Triethylene Glycol Vapor at Various Relative Humidities and Temperatures (Page 1 only). Science
    - Editorial (1947) Glycol Vapors for Disinfecting Purposes. JAMA
    - The Rate of Bactericidal Action of Triethylene Glycol Vapor on Microorganisms Dispersed into The Air in Small Droplets
    - Editorial (1943) Disinfection of the Air with Triethylene Glycol Vapor. American Journal of Medicine. Vol. 7, No. 3
    - Nagy, R. (1950) Effect of Propylene and Triethylene Glycol on Atomized *E. coli*. Science. Vol. 112

- Rudnick, S. (2009) Inactivating Influenza Viruses on Surfaces Using Hydrogen Peroxide or Triethylene Glycol at Low Vapor Concentrations. Federal Aviation Administration (FAA) Final Report

Note: Publications were reviewed to supplement product-specific efficacy data where appropriate.

EPA/AD has had several meetings with Grignard Company, LLC, to discuss technical details of the Section 18 application; meeting dates include: 9/11/2020, 10/2/2020, 10/9/2020, 10/16/2020, 10/23/2020, 10/30/2020, 11/6/2020, 11/13/2020, 11/20/2020, 12/4/2020, 12/9/2020, 12/11/2020, 12/18/2020, 12/30/2020, 1/4/2021, and 1/8/2021.

A synopsis of the revised Section 18 application (dated 11/17/2020) is included in the Appendix section of this review.

II PROPOSED LABEL

Submitted: 1/5/2021 (**Filename: Grignard Pure LABEL SEC 18_12220_V19 (002).pptx**)

The product is for sale, distribution, and use only in the States of Tennessee and Georgia under FIFRA § 18 Public Health Emergency Exemption Numbers 20VT01, 21TN02, and 21GA02.

Required: Post stickers or signs at each entrance to/interior a treated space.

(Filename: Grignard Pure Placard Layout_v 2_1 5 21.pptx)

According to the proposed label, the product is designed to reduce the level of airborne SARS-CoV-2 virus, based on testing with a surrogate virus. The product is for use in indoor occupied and unoccupied spaces including:

- Health care facilities (e.g. hospitals, nursing homes, medical offices, dental offices) except in resident /in-patient rooms and in the critical health care areas: i.e. emergency rooms, hospital operating rooms, and intensive care units;
- Mass transit, i.e. intrastate buses, trains, subways;
- Ice rinks
- Food processing facilities;
- Government facilities (e.g. court houses, motor vehicles, agencies, correctional facilities, social services agencies);
- Breakrooms, locker rooms, bathrooms, lobbies, elevators, eating areas, and food preparation areas in buildings where commercial activity is deemed essential by the state.

Directions for Use

- Grignard Pure is for use with only Grignard Pure-certified air treatment equipment and sensors. Read and follow the User Manuals for complete directions on how to operate this equipment (Manuals and more information available at GrignardPure.com/Solutions).
- Grignard Pure is to be used in full concentration and cannot be diluted.

The amount of Grignard Pure product needed to maintain required levels (see Table 1) will vary depending on the following parameters (confer with your Grignard Pure-authorized dealer or Grignard Pure-certified installer to confirm specific requirements for your system):

- Size of room or interior space
- Air exchanges per hour;
- Temperature and humidity;
- Hours of operation for your office/facility/venue

Table 1 (extracted from label).

Measurement Method	Visual Assessment of Haze Density	Particle Sensor Reading for GP	Equivalent Active Ingredient Concentration
Minimum	Non-visible	1.66 mg/m^3	1.04 mg/m^3
Maximum	Light Moderate	9 mg/m^3	5.62 mg/m^3

Standard Machine Set-Up and Use

Machines and equipment used must be certified by Grignard Pure and installed by Grignard Pure-certified installers. Use with any other machines, equipment, or systems is prohibited. Consult with your Grignard Pure-authorized dealer or Grignard Pure-certified installer to determine optimal installation specifications for your indoor space, to include: portable device vs. HVAC integration; number and placement of devices; sensor

technology for maintaining required levels vs. visual observation.

There are two types of machine implementation and use**:**

- **HVAC integration***:* Where Grignard Pure equipment is integrated into a building's HVAC system. This installation MUST be performed by a Grignard Pure-certified installer. Greatest efficiency is achieved when the equipment is connected directly to the HVAC unit controls, so that the equipment will turn on when the HVAC equipment has a call for operation.

- **Portable device placement***:* Where Grignard Pure equipment is placed in strategic locations in an interior space. The specific equipment placement shall be determined by a certified Grignard Pure-certified installer.

In both cases, machines should be operated, cleaned and serviced in accordance with the User Manual (also available at GrignardPure.com/Solutions).

For maximum effectiveness, the best achieved air treatment level will be reached when the temperature is between 65°F -85°F and relative humidity is between 25% -60%.

Measuring Proper Product Concentration

Apply the product to achieve an airborne concentration of Grignard Pure according to Table 1.

There are two methods for ensuring a proper concentration of Grignard Pure in the air:

- Sensor: Maintain a concentration between 1.66 mg/m^3 to 9 mg/m^3 to produce a Time Weighted Average below 4.8 mg/m^3 of GP (3 mg/m^3 AI) as measured by a certified sensor, purchased through an authorized dealer and installed by a certified installer. (These concentrations correspond to a range of a non-visible to light moderate haze.)
- Visual Observation: For installations where concentration is not sensor-controlled, visual assessment must replace the use of sensors. Maintain a light air treatment level by running the device for a few minutes, every 30 minutes (Times will vary depending upon unique equipment output, and volume of space to be treated). In this method, the observation of a very light to light haze in the air will confirm proper levels of product concentration for achieving effective, continuous levels of air treatment. Refer to GrignardPure.com/Visual Assessment for directions on how to effectively perform visual assessment. Recommended frequency of visual assessment monitoring is at least once every hour.

Continuous Machine Use

Do not apply product in a way that results in exposure to any individual for more than 12 hours. Maintain air circulation at all times to ensure any Grignard Pure residue in the filter has dried out.

III INSTALLATION MANUALS/USER MANUALS/CERTIFICATION MATERIALS

In the applicant's response to EPA's Technical Questions (dated 11/25/2020, the following information was provided to address the requests for user manual and training documents.

Applicant's Response: Grignard has worked with Chauvet to revise user manuals to clarify that these user manuals are to be followed when using Grignard Pure. Please note these machines have been using the Chauvet PHF (haze fluid) which is very close in composition to Grignard Pure. The manuals are available for inspection on the Grignard Pure website (Filename: EPA_Technical Questions for Grignard Pure_112520_Final; included with submitted documents in I BACKGROUND section).

Consistent with the applicant's response, instructions were provided to access the information on the website. Information from website is detailed below with accompanying screenshots; briefly,

Training

The website includes the following information:

> Grignard Pure is in final evaluation of third-party training partners. The partner will design the Training Programs for the certification levels referenced on the Certifications Page.
>
> Actual training modules will be accessible via direct links to the custom training program design by the third party-partner (which will be a combination of webinar and manual formats). The training framework, detailed below, was provided and accessible on the website.

The Grignard Pure—Training and Certification document

Official Grignard Pure certification levels and training requirements:

1. Certified Installer Course
    - Audience: Anyone installing GP in portable setup or into HVAC system, distributor, integrator
    - Other Required Trainings: Consultant: End User
    - The purpose of this protocol is to outline the optimal procedure for applying Grignard Pure air treatment through portable units and HVAC installations
    - For ALL Applications of Grignard Pure

        - Set-up of the End User Registration with each end user; advise on additional infrastructure needs (i.e. improving ventilation to reduce viral loads)
        - Legal acknowledgements
        - Grignard Pure system requirements
        - Proper machine selection guidelines
        - HVAC/indoor airflow considerations, guidelines, and important settings
        - Machine run times and on/off protocols
        - Target and acceptable concentration level ranges
        - Troubleshooting and Maintenance
        - GP Portal Training
            - WiFi connection
            - Data capture
            - Product/Installer registration and activation
    - For Portable Units
        - Machine placement for portable units
        - Controller—Set-up, Use, Settings, Protocols
        - Booster fans
        - Alternative to the booster fans
        - Sensors
    - For HVAC Installed Units
        - HVAC install process
            - Step by step process
            - Power Considerations
            - DMX install and power
        - Balancing
            - Initial sensor placement for setup and testing
            - Permanent sensor placement
            - HVAC air flow considerations initial adjustment
        - Duct work considerations, requirements, modifications
        - Resevoir placement for refilling
        - Sensors should relate to actuators which turn machine on/off, open/close dampers, and sense when HVAC blower fan is on/off
    - Equipment
        - Wireless Installations
            - Dispersal Units
                - AmHaze ECO
                - AmHaze Stadium
                - AmHaze Whisper
                - Hurricane Haze 1DX
            - Sensors and Sensor Kits
            - System Management Unit (SMU)
                - Unit description
                - How it works and what it does
                - How to pair sensors and the DMX to the SMU
                - Radio frequency connection and WiFi connections to Cloud System
            - Controller (DMX)
        - Hardwire Installations

- Atomizer
- Controller
- Sensor

2. Customer Consultant/Sales Course (estimate 1 hour)
    - Audience: Certified Installers; All vertical partner sales and customer facing teams and their sub-distributors, basically anyone who is representing, selling, or discussion GP in a commercial manner
    - Other Required Trainings—End User; Installer (certification # not needed)
        - GP product description, features and benefits
        - Brief history of development
        - An understanding of the product and how to respond to questions in a unified manner
        - COVD-19 spread data (CDC latest)
        - COVID-19 Risk Index
        - How it works to de-activate the virus
        - How it gets dispersed , measured, etc. in indoor space
        - Health & Safety Basics
        - Efficacy data
        - How GP compares to List N (surface) disinfectants
        - How GP compares to other 'air treatment' technologies, competitive advantages, EPA certifications, etc.
        - How to position GP against other solutions
        - Luminator video and NAT video among others should be included
        - Treated (not Protected) by Grignard Pure Sticker
        - Target markets and sample customer (or potential) examples
        - About Grignard Company
        - About Grignard Pure team and Science team and organizations
        - Latest testing sites and information
        - How to 'tell the story'
        - Links to other Content Resources—videos, FAQs, User Manuals, Website, Comparison Technology guide, Power Point (which needs update); H & S guide
3. End user Registration Certification Course (estimate 1 hour or less)
    - Training Audience – End user customers in any setting; Anyone using the system on a regular basis, filling the dispersal unit(s), turning on/off, reading sensors, etc.
    - Other Required Trainings – None
        - Register as a "New Customer" and perform specific tasks which will include
        - Complete the system registration (Name/Address/Contact/Equipment
        - Entering the installer certification number
        - Confirm EPA and legal acknowledgements and indemnifications

- Accessing the dispersal unit
- Operating the dispersal unit
- Sensor reading/visual observation instruction
- Monitoring and reporting requirement
- Collecting data science study variable
- Ongoing monitoring and maintenance of the system
- Equipment refilling and cleaning
- Data entry (i.e. monthly product lot number
- Treated by Grignard Pure" on-premise signage posting requirement
- Basic troubleshooting steps
- General FAQs

User Manuals

Dispersion Units

Amhaze ECO

- Safety Notes
  - Drain the tank before transporting the product
  - This product is for indoor use only
  - Mount this product in a location with adequate ventilation, at least 20 inches (50 cm) from adjacent surfaces
  - Only use Chauvet (PHF) fluid or Grignard Pure.
  - Do not add anything to the fluid.
  - The maximum ambient temperature is 113°F (45°C). Do not operate this product at higher temperature.

Amhaze Stadium

- Safety Notes
  - Drain the tank before transporting the product
  - This product is for indoor use only
  - Mount this product in a location with adequate ventilation, at least 20 inches (50 cm) from adjacent surfaces
  - Only use Chauvet (PHF) fluid or Grignard Pure.
  - Do not add anything to the fluid.
  - The maximum ambient temperature is 113°F (45°C). Do not operate this product at higher temperature.
- Preparation for Operation
  - Open the flight case
  - Pull out the fluid tank and remove the cap
  - Verify that the two plastic hoses attached to the inside of the cap are in place and in good condition
  - Pour Chauvet (PHF) haze fluid or Grignard Pure inside the tank, and re-cap
  - Reinsert the tank
  - Make sure that the plastic hose that goes from the cap to the hazer is not bent.
  - Plug in power and wait approximately 30 seconds for warm-up to complete

Amhaze Whisper

- Safety Notes
  - Depending on the amount of haze generated, all haze machines may set off smoke detectors
  - Drain the tank before transporting the product
  - This product is for indoor use only
  - Mount this product in a location with adequate ventilation, at least 20 inches (50 cm) from adjacent surfaces
  - Only use Chauvet (PHF) fluid or Grignard Pure.
  - Do not add anything to the fluid.
  - The maximum ambient temperature is 113°F (45°C). Do not operate this product at higher temperature.
- Preparation for Operation
  - Open the flight case
  - Pull out the fluid tank and remove the cap
  - Verify that the two plastic hoses attached to the inside of the cap are in place and in good condition
  - Pour Chauvet (PHF) haze fluid or Grignard Pure inside the tank, and re-cap
  - Reinsert the tank
  - Make sure that the plastic hose that goes from the cap to the hazer is not bent.
  - Plug in power and wait approximately 30 seconds for warm-up to complete

Hurricane Haze 1DX

- Safety Notes
  - Depending on the amount of haze generated, all haze machines may set off smoke detectors
  - This product is for indoor use only
  - Always place this product in a location with adequate ventilation, at least 20 inches (50 cm) from adjacent surfaces
  - Only use Chauvet water-based fluid or Grignard Pure.
  - Drain the tank before transporting the product
  - Do not add anything to the fluid.
  - The maximum ambient temperature is 113°F (45°C). Do not operate this product at higher temperature.

Sensor Kit

- **SMU**
- **Controller**
- **Sensor**

HVAC Installation Manual

- You will receive a complete Grignard Pure System with everything needed for installation except hardware for hanging the Dispersal Unit and ducting to connect the Dispersal Unit to the HVAC system.
- We recommend reading the installation guide all the way thru so that you can better prep for installing the unit. There are several parts that you will need to configure or fabricate to complete the installation.

- You will need a power source at the location of the dispersal unit with 3 available outlets. If you have filters in your HVAC become damp, this is OK but be sure to run the fan for some time after the Grignard Pure system is turned off in order to dry out the filters.
- **Step 1: Install the Dispersal Unit**
  Mount the dispersal unit near the supply side of the air handler.
    - You will need to run a duct from the Dispersal Unit into the main duct of your HVAC System.
        - You should have at least 16 inches between the output vent of the dispersal unit and the HVAC duct work.
        - The duct that connects the dispersal unit to the HVAC duct work should be straight.
        - Best done with 4-inch stove pipe.
        - Seal all connections with metal duct tape
    - The atomized product comes out of the unit hot and the output area will get hot. DO NOT USE thin flexible ducting like dyer vents. It may melt or burn.
    - Make the unit as accessible as possible the client will need to fill the chemical reservoir on a regular basis.
    - Fill the reservoir with Grignard Pure fluid.
    - An ideal location to connect into is about 4 feet from the fan.
- **Step 2: Install Dispersal Ducting Inside the main HVAC Duct**
    - At the main duct cut hole big enough to fit a 90 degree elbow with an extension piece at least 14 inches long inside the main duct.
    - The 14-inch extension will point down the ducting in the direction of the air flow. This will allow the product to be evenly incorporated into the existing circulated air flow.
    - The far end of the 14-inch stove pipe must be flared out resembling a mushroom.
        - Example:
            - To flare the ends cut 1.5-inch deep, 1.5 inches apart all around the dispersal ductwork.
            - Seal the gaps in the flare cuts with metal duct tape.
    - If the duct work is a “T” configuration servicing separate area of the workspace being treated
        - You will need to install an internal T of dispersal ducting to disperse the air evenly through both ends of the duct
        - Install extensions, reaching at least 14 inches past the main supply into the next duct piece, in both directions. o be sure to flare both ends
    - Secure you [sic] new duct work to the existing HVAC duct, with a self-tapping screw, so that the systems are tight to minimize vibration or gaps.
- **Step 3: Connect dispersal unit to HVAC ducts**
    - Connect the duct coming off the dispersal unit to the Elbow or T connector that you have inside the HVAC duct
    - Fasten pieces together with a self-tapping screw.
    - Seal all connections with metal duct tape.
    - Seal the hole in the main duct around the dispersal duct

You will receive a complete Grignard Pure System with everything needed for installation of your Wireless Sensor and Control units.

Step 1: Install antenna unit

- The dispersal unit should only be running if the fan in your HVAC is running in order to move the product through the duct work.
- The HVAC fan should be set to run 24/7 to ensure proper dispersal of the product.
- If you can't run the fan 24/7 install the Antenna Unit
    - Close the "C" clamp end of the antenna around the power line running to the fan.
        - When the power is on, the clamp will detect the electro-magnetic field form outside the cables covering and signal the dispersal unit that it's OK to run.
        - This is called the "Hall Effect"
        - Do not cut into the power cable during installation.
    - Leave small square tile with green circle outside of the air handler.
        - This is the wireless antenna.
    - Plug antenna unit into power source

Step 2: Connect senor receiver unit to Dispersal Unit.

- This is the unit without air vents in the base faceplate.
- The volume knob or dial on the dispersal unit must be set to "OFF" in order for the unit to take commands form the wireless monitoring and control system.
- Connect black plug on the receiver to the DMX IN outlet on the face of the Dispersal Unit.
- Plug receiver unit into power source.
- The light on the front of the unit will blink briefly.

Step 3: Three Sensors are included in this installation.

- The sensor units have air vents in the faceplate
- All sensors need to be at least 4 feet off the floor
    - Thermostats are usually 4.6 feet off the floor
    - We want to be measuring the air where the people are.
- All sensors need an outlet for power
- All sensors must be place so that vents are not blocked
- Sensors must be placed in an area with good air flow
    - Sensor "A" is placed in the vicinity of the first ceiling register from the Dispersal Unit.
    - Sensor "B" is placed in the vicinity of a ceiling register about halfway from the dispersal unit to the end of the duct run.
    - Sensor "C" is placed in the vicinity of a ceiling register at the end of the duct run.
- Each sensor will report back readings every second to the control units and to our web portal.
    - Incoming readings can be visually monitored, in real time, via the web portal.
    - The web portal can be used to set or adjust the product dispersal via:
        - Time and Date settings
        - Dispersal Unit - Fan Speed
        - Dispersal Unit - Product Application Levels

- Feedback from sensor readings in the treated areas

Step 4: Find a centrally located position for the Sensor Management Unit (SMU).

- The SMU talks to all the modules you have installed.
- The SMU will need a power source.
- The SMU ships with a wall mounting kit but can also just rest on a table, desk or shelf.
- When functioning properly the SMU will glow solid green on top.
- The SMU should be within 50 feet of the sensors and controller units.
    - If you have an installation that requires more than 50 feet of distance you will need a repeater unit to extend your range.
- Plug in the SMU to a power source.
- Check for pairing:
- Press the bottom of the three buttons on the front of the SMU and hold for 12 seconds to pair with the local WI-FI.
- Plug in each sensor and check for pairing, once the whole system is powered up, sensors and SMU.
    - Insert a small pin or paper clip end into the little hole on the top of the sensor for 1 second or less.
    - If the light flashes Green - Red – Green you are paired.
    - If the light stays red you are not paired.

Step 5: Connect to Grignard Pure Cloud application

- Connect to the internet via a local WI-FI Signal
- Once connected to the internet you will need to setup your portal
    - Log into Grignard Pure Cloud
    - Register system and set passwords
    - Hit Reports on the left-hand side of the screen
    - Choose Sensors
    - Choose PM Sensor to view the real-time sensor readings

Step 6: Set customer specific control settings

- Your system will have shipped with generic settings related to the square footage you are trying to protect.
- All spaces and HVAC setups are unique in some way. These differences will have an effect on the air patterns of the space you are trying to protect. As a result, you may need to adjust the control settings accordingly.
- In Administrator mode check sensor levels and set Dispersal Unit to desired levels to balance system out.
    - Run the system for 30 minutes with the default settings.
    - After 30 minutes you should be able to tell where there are dispersion issues by reading the sensor data or by a visual examination of the space.
    - Via the portal you can adjust the various control features until you've reached appropriate levels of coverage.
    - It is OK to move sensors around to various areas of concern; all workspaces have different layouts and air patterns. Adjust to the space in order to get an accurate treatment reading.
- If you are seeing readings that indicate little or no product in specific areas, there is likely to be an issue in the HVAC itself.
    - Dampers closed

    - Filters in the path
    - Holes in the conduit
    - etc.
- Do not use or attempt to calibrate if the space you are protecting has open doors or windows. These will let fresh air in and the product out making reliable readings impossible.

Hard-wired Installations: Equipment and User Manuals

System Overview Renew Air Treatment Solution, Version 1.0

The Renew System Controller obtains data from the Sensor, to monitor levels of Grignard Pure in the air and continuously adapts the amount of product to be dispersed by the Atomizer. This enables the system to maintain the pre-determined effective concentration at all times. The Controller monitors a PM2.5 laser diffraction particle Sensor, once per second. As with any closed loop control, there are several configuration settings that can be changed to maximize the performance of the control loop. For example, a small volume area with little fresh air replenishment will detect the presence of atomized solution much faster than a large volume are with high fresh air replenishment rates. The initial settings for the small volume space would be lower than for the large volume space.

Certifications (provided on the website)

- **GP Certified Installer (HVAC independents-master distributor integrators): Grignard Pure requires each installer to pass its training program. Steps include:**
    - Advanced Installer level training in Grignard Pure system requirements, components, design, implementation and testing, operation, and maintenance, and end-user training and registration;
    - Set-up of the End User Registration with each end user; advise on additional infrastructure needs (i.e. improving ventilation to reduce viral loads
- **End User Registration Certification**
    - Register as a “New Customer” and perform specific tasks which will include (but may not be limited to): complete the registration (Name/Address/Contact/Equipment); agree to collect data science study variables; enter the installer certification number; and confirm EPA and legal acknowledgements and indemnifications.
    - Complete a webinar-based training program to qualify for ongoing monitoring and maintenance of the system, with training modules to include: Equipment refilling and cleaning; sensor reading/visual observation instructions; monitoring and reporting requirements; data entry (i.e. monthly product lot number); “Protected By Grignard Pure” on-premise signage posting requirements; and general FAQs.

IV SYNOPSIS OF SUBMITTED EFFICACY DOCUMENTS

Table 1: Summary of Submitted Studies

Study Number	Product Tested/Study Number	Microorganism Tested	Haze Density (Qualitative)	Amount Used/Tested Concentration (g)	Duration	Log Reduction
1	Grignard Pure (Lot No. 040820A) with Hurricane 1800 Flex Machine (NG15232) Study Dates: 13APR2020-23MAY2020	MS2	Study text: Information not provided in the study; Study saved as: Moderate fog	28	10 minutes 1.5 hours 3 hours	> 3.12* > 2.02** > 1.82
2	Grignard Pure (Lot Nos. 040820A and 040820B with Amhaze Stadium Haze Machine (NG15621) Study Dates: 13APR2020-18JUN2020	MS2	Study text: Light to light-moderate; Study saved as: Observations: According to the images however, light-moderate appears to be more pronounced at 3-minute contact time	Information not provided	3 minutes 15 minutes 27 minutes	2.08 2.23 >2.16
3	Grignard Pure (Lot Nos. 040820A and 040820B) with Hurricane 1800 Flex Machine (NG15621) Study Dates: 13APR2020-19JUN2020	MS2	Study text: Light to light-moderate included in the study; Study saved as: Light Haze Observations: According to the images however, 3 images with varying haze	Information not provided	3 minutes 15 minutes 27 minutes	2.55 >3.01 >2.88

			densities provided for time zero, while a 27-minute contact time is similar in haze to time zero			
4***	Grignard Pure (Lot Nos. 040820A and 040820B) with Amhaze Stadium Haze Machine NG15621) Study Dates: 13APR2020–23JUN2020	MS2	Study text: Light to light-moderate; Saved as: Light haze Observations: Haze densities look identical for each timepoint	Information not provided	1 minute	2.94***
						2.99***
						3.34***
						3.34***
					15 minutes	2.92***
						2.97***
						3.31***
						3.32***
					60 minutes	3.53***
						3.57***
						3.92***
						3.93***
5	Grignard Pure (Lot No. 061820) with Amhaze Stadium Haze Machine with remote (NG16240) Study Dates: 25AUG2020–02SEPT2020	MS2	Test 1 (Non-Visual Haze)	4.11	30 seconds	1.72
				6.74	15 minutes	3.07
				1.72	60 minutes	2.79
			Test 2 (Very Light Haze)	10.7	30 seconds	2.80
				14.2	15 minutes	2.96
				6.89	60 minutes	2.70
6	Grignard Pure Lab #041320C with Hurricane 1800 Flex Machine	Human Coronavirus (Carrier Based Tested), ATCC VR-740, Strain 229E	Test study: Moderate; Observations: Difficult to ascertain haze densities from the images provided on page 10 of the study (Page 6 is missing from the study)	Total amount used: 69.98	3 hours	Low: 2.25****
						Middle: 2.00****
						High: 2.25****
7	Grignard Pure Lab #041320C with Hurricane 1800 Flex Machine	Human Adenovirus type 5. ATCC VR-5, Strain Adenoid 75	Test study: Moderate; Observations: Difficult to ascertain haze densities from the images provided on	Total amount used: 91.98	3 hours	Low: 0.60****
						Middle: 2.35****
						High: 1.85****

			page 11 of the study.			

*Calculated according to baseline time zero; not same time period of 10-minute contact time.
**Calculated according to control counts for 1 hour; no control counts for 1.5 hour
***Log reduction calculated based on time zero control counts from previous studies (NG15232 and NG15621); no time-specific control carrier counts were used to calculated log reductions. Consequently, this may represent an elevated log reduction not accounting for natural die off especially for the 15-minute and 60-minute contact times. Of note, test (product released first followed by nebulized MS2) conduct differs from other tests (nebulized MS2 followed by product).
****Average dried virus controls were the same for time zero and 3- hours/or elevated for a replicate.

Red Outlined Box= Aerosolized Studies
Blue Outlined Box = Carrier-Based Studies
Study relied upon for Section 18 application
Studies considered but to a lesser extent for Section 18

1. Evaluation of Bioaerosols and Grignard's Test Substance

Study Identification Number: NG15232
Control Chamber Run: 04MAY2020
Test Chamber Run: 05MAY2020
Test Repeat: 22MAY2020; Due to low recovery of the test microorganism from the time zero samples, the test was repeated.

Study Synopsis

- Test Substance: Grignard Pure
- Test Device: Hurricane 1800 Flex (Chauvet DJ)
- Test was initiated by aerosolizing the microorganisms per the nebulizers and allowing the concentration to reach the required PFU/m^3. The nebulization time was 60 minutes. Once the concentration was reached, a time zero sample was taken then the device was run for the specified contact time and an additional sample was taken at each contact time (10 minutes, 1.5 hours, and 3 hours).
- The decontamination process was run, 4 hours of UV exposure, prior to scientists entering the testing chamber.
- Samples are enumerated using standard dilution and plating techniques.
- Microbial concentrations were determined after appropriate incubation times.
- Reductions of microorganisms are calculated relative to concentration of time zero or corresponding control run sample as applicable.
- Test substance (511 g) was weighed out into the fog fluid container of the test device and the device was primed as per study sponsor instructions. The test substance still in the test device was weighed after the priming and there was 492 g remaining. The test substance was weighed after the study was completed and there was 464 g remaining.
- No organic soil included
- The wired remote was set per the study sponsor instructions with the interval set to 30 minutes, duration set to 3 minutes and output set to the 3rd dash mark
- 10-minute contact time is compared to the time zero of the baseline run as the test microorganism's natural die off and settling at 10 minutes will be negligible.

2. Evaluation of Bioaerosols and Grignard's Test Substance

Study Identification Number: NG15621
Control Chamber Run: 17JUN2020
Test Chamber Run: 17JUN2020

Study Synopsis

- Test Substance: Grignard Pure
- Test Device: Amhaze Stadium Haze (Chauvet DJ): Per the study sponsor's instructions Amhaze Stadium Haze machine was set to a fan speed of 50% and a haze output of 100%. The device was run for 30 seconds before a light to light -moderate level of haze was achieved in the NPAC chamber.
- Test was initiated by aerosolizing the microorganisms per the nebulizers and allowing the concentration to reach the required PFU/m^3. Once the concentration was reached, a time zero sample was taken then the device was run for the specified contact time and an additional sample was taken at each contact time (3, 15, and 27 minutes)
- The decontamination process was run, 4 hours of UV exposure, prior to scientists entering the testing chamber.
- Samples are enumerated using standard dilution and plating techniques.
- Microbial concentrations were determined after appropriate incubation times.
- Reductions of microorganisms are calculated relative to concentration of time zero or corresponding control run sample as applicable.
- Humidity/temperature were recorded for baseline during the test.
- No organic soil included
- Per the study sponsor instruction Amhaze Stadium Haze Machine was set to a fan speed of 50% and a haze output of 100% device was ran for 30 seconds before a light to light-moderate level of haze was achieved in the NPAC chamber.

3. Evaluation of Bioaerosols and Grignard's Test Substance

Study Identification Number: NG15621 (duplicate study number)
Control Chamber run: 17JUN2020
Test Chamber run: 18JUN2020

Study Synopsis

- Test Substance: Grignard Pure
- Test Device: Hurricane 1800 (Chauvet DJ); per study sponsor instruction Hurricane 1800 Flex output was set to the third dash mark. Manual button was held for 3 seconds before a light to light-moderate haze level was achieved in the NPAC chamber.
- Test was initiated by aerosolizing the microorganisms per the nebulizers and allowing the concentration to reach the required PFU/m3. Once the concentration was reached, a time zero sample was taken then the device was run for the specified contact time and an additional sample was taken at each contact time (3, 15, and 27 minutes)

- The decontamination process was run, 4 hours of UV exposure, prior to scientists entering the testing chamber.
- Samples are enumerated using standard dilution and plating techniques.
- Microbial concentrations were determined after appropriate incubation times.
- Reductions of microorganisms are calculated relative to concentration of time zero or corresponding control run sample as applicable.
- Humidity/temperature were recorded for baseline and during the test.
- No organic soil included

4. Evaluation of Bioaerosols and Grignard's Test Substance

Study Identification Number: NG15621 (duplicate study number)
Control Chamber run: No control chamber run
Test Chamber run: 22JUN2020

Study Synopsis

- Test Substance: Grignard Pure
- Test Device: Amhaze Stadium Haze
- Test was initiated by aerosolizing the microorganisms per the nebulizers and allowing the concentration to reach the required PFU/m^3. Once the concentration was reached, a time zero sample was taken then the device was run for the specified contact time and an additional sample was taken at each contact time (1 minute, 15 minutes, and 60 minutes)
- The decontamination process was run, 4 hours of UV exposure, prior to scientists entering the testing chamber.
- Samples are enumerated using standard dilution and plating techniques.
- Microbial concentrations were determined after appropriate incubation times.
- Reductions of microorganisms are calculated relative to concentration of time zero or corresponding control run sample as applicable.
- Humidity/temperature were recorded for baseline and during the test.
- No organic soil included
- A second test with Amhaze Stadium Haze Machine was performed. The device was set to 50% fan speed and 100% haze output and the manual button was held for ~ 5 seconds and a light to light-moderate haze was achieved prior to nebulization of test microorganism. The test microorganism was then nebulized while maintaining a light to light-moderate haze for 60 minutes. Air samples were then taken at 1 minute, 15 minutes and 60 minutes after nebulization completion. Because the test substance was released prior to nebulization a time zero was not taken and the nebulization of the test microorganism cannot be confirmed. Since a time zero was not taken log reduction calculations could not be made for this portion of the test.

5. Evaluation of Bioaerosols and Grignard's Test Substance
Study Identification Number: NG16240
Baseline Run Date: 25AUG2020- 26AUG2020
Test 1, Non-Visual Amount of Haze: 27AUG2020 – 28AUG2020
Test 2, Very Light Haze: 01SEP2020 – 02SEP2020

Study Synopsis

- Test Substance: Grignard Pure
- Test Device: Amhaze Stadium with remote
- Test was initiated by aerosolizing the microorganisms per the nebulizers and allowing the concentration to reach the required PFU/m^3. Once the concentration was reached, a time zero sample was taken then the device was run for the specified contact time and an additional sample was taken at each contact time (30 seconds, 15 minutes, and 60 minutes)
- The decontamination process was run, 4 hours of UV exposure, prior to scientists entering the testing chamber.
- Samples are enumerated using standard dilution and plating techniques.
- Microbial concentrations were determined after appropriate incubation times.
- Reductions of microorganisms are calculated relative to concentration of time zero or corresponding control run sample as applicable.
- Humidity/temperature were recorded for baseline and during the test.
- No organic soil included
- **Test run 1** was performed with the following parameters per the Study Sponsor instructions;
    - Chamber was dosed with test substance every 10 minutes for 10 seconds to achieve a non-visual level of haze in the chamber;
    - Amhaze Stadium remote was set to T001:255, T002: 02;
    - Particle counter readings were taken at the sampling times and recorded.
- **Test run 2** was performed with the following parameters per Study Sponsor instructions;
    - Chamber was dosed with test substance every 30 minutes for 30 seconds to achieve a very light level of haze in the chamber;
    - Amhaze Stadium remote was set to T001:255, T002: 040;
    - At time 30 the particles counter was >20 mg/m^3 the decision was made to only dose room for 10 seconds so that haze level in room did not get too high;
    - Particle counter readings were taken at the sampling times and recorded
- Extech VPC300 particle counter experienced a malfunction prior to test run 2 and was not used in the testing that occurred on 01SEP2020
- A baseline chamber run was performed to determine the micro-droplet distribution of the test substance at a non-visual level of haze with the following parameters: Amhaze remote was set to T001:255, T002:020, chamber was dosed every 10 minutes for 10 seconds, particle counter readings were observed and recorded.
- A baseline chamber run was performed to determine the micro-droplet distribution of the test substance at a non-visual level of haze with the following parameters: Amhaze remote was set to T001:255, T002:020, chamber was dosed every 30 minutes for 30 seconds, particle counter readings were observed and recorded.

6. Virucidal Efficacy of a Disinfectant Applied to a Room Via a Fogging, Misting or Vaporizing Device, Study conducted by Analytical Lab Group (ALG)

Study completion date: May 28, 2020

Revised report date: July 1, 2020
Tested product: Grignard Pure Lab #041320C

Study Synopsis

- Test substance: Grignard Pure Lab #041320C
- Device: Hurricane 1800 Flex Machine
- Virus tested: Human Coronavirus, ATCC VR-740, Strain 229E
- Exposure time: 3 hours
- Exposure temperature: 25-29°C (prior to testing, the room was brought to temp before turning off the air handling system; Start: 24.7°C; 3 hours: 23.50°C)
- Exposure humidity: Start: 45.03%; 3 hours: 66.65%
- Organic soil load: 1% fetal bovine serum
- Prior to using the machine, the initial weight of the test substance was taken. The Hurricane 1800 Flex Machine was placed on the floor of the testing room (~10^4 m^3), in a complete horizontal position at a distance of ~ 5 feet from the low level carrier placement. The Hurricane 1800 Flex was controlled via a wired timer controlled. The Hurricane 1800 Flex was allowed to heat up for 3 -5 minutes. With the fluid intake tube in the test substance bottle, the manual button on the remote control was pressed in order to prime the machine. The test substance was then weighed again following the priming and returned to the Hurricane 1800 Flex for use in testing.
- For each carrier, a 200 µL aliquot of the test virus was added to the surface of the carrier. The virus was air dried at 10°C-30°C until visibly dry (20 minutes). Prior to the start of the test, the room temperature was 25-29°C. The air system was turned off at the start of testing to prevent interference with the test device. In order to maintain a relative humidity of 45-65%, a humidifier was added to the testing room.
- One carrier was placed at the low height, middle height and high height in the testing room. The distance from the device were as follows: Low: ~ 5 feet; Middle: ~6.6 feet; High: ~12.4 feet. The device was operated with INTERNAL set to 30 minutes and DURATION set to 5 seconds. No adjustment was required during testing. Per the Sponsor provided concentration determining chart, the haze level in the testing room was maintained at moderate haze level (from a distance of ~ 10 feet) for the Sponsor specified exposure times.
- Following exposure, a 2.0 mL aliquot of test medium was added to each carrier and scraped with a cell scraper to resuspend the contents (10^{-1} dilution). The test medium was collected, passed through individually prepared Sephadex columns and then serial 10-fold dilutions were performed. Each dilution was assayed for infectivity and/or cytotoxicity.
- Controls included those for dried virus control, cytotoxicity control, and neutralization control.

7. Virucidal Efficacy of a Disinfectant Applied to a Room Via a Fogging, Misting or Vaporizing Device Against Human Adenovirus Type 5, Study conducted by Analytical Lab Group (ALG)

Study completion date: May 28, 2020
Revised report date: July 1, 2020
Tested product: Grignard Pure Lab #041320C

Study Synopsis

- Test substance: Grignard Pure Lab #041320C
- Device: Hurricane 1800 Flex Machine
- Virus tested: Human Adenovirus, ATCC VR-5, Strain Adenoid 75
- Ready-to-use preparation
- Exposure time: 3 hours
- Exposure temperature: 25-29°C (prior to testing, the room was brought to temp before turning off the air handling system; Start: 24.73°C; 3 hours: 23.75°C)
- Exposure humidity: Start: 54.38%; 3 hours: 48.10%
- Organic soil load: 1% fetal bovine serum
- Prior to using the machine, the initial weight of the test substance was taken. The Hurricane 1800 Flex Machine was placed on the floor of the testing room (~10^4 m^3), in a complete horizontal position at a distance of ~ 5 feet from the low level carrier placement. The Hurricane 1800 Flex was controlled via a wired timer controlled. The Hurricane 1800 Flex was allowed to heat up for 3 - 5 minutes. With the fluid intake tube in the test substance bottle, the manual button on the remote control was pressed in order to prime the machine. The test substance was then weighed again following the priming and returned to the Hurricane 1800 Flex for use in testing.
- For each carrier, a 200 µL aliquot of the test virus was added to the surface of the carrier. The virus was air dried at 10°C-30°C until visibly dry (20 minutes). Prior to the start of the test, the room temperature was 25-29°C. The air system was turned off at the start of testing to prevent interference with the test device. In order to maintain a relative humidity of 45-65%, a humidifier was added to the testing room.
- One carrier was placed at the low height, middle height and high height in the testing room. The distance from the device were as follows: Low: ~ 5 feet; Middle: ~6.6 feet; High: ~12.4 feet. The device was operated with INTERNAL set to 30 minutes and DURATION set to 5 seconds. No adjustment was required during testing. Per the Sponsor provided concentration determining chart, the haze level in the testing room was maintained at moderate haze level (from a distance of ~ 10 feet) for the Sponsor specified exposure times.
- Following exposure, a 2.0 mL aliquot of test medium was added to each carrier and scraped with a cell scraper to resuspend the contents (10^{-1} dilution). The test medium was collected, passed through individually prepared Sephadex columns and then serial 10-fold dilutions were performed. Each dilution was assayed for infectivity and/or cytotoxicity.
- Controls included those for dried virus control, cytotoxicity control, and neutralization control.

Technical Documents Used to Correlate Haze Densities to Actual Use Concentrations

1. Determine Total Concentration of Triethylene Gylcol in the Air When Utilizing Grignard Pure and Determine Correlation of Air Concentrations to Aerosol Monitor Measurements, dated 9/23/2020
    - The study aimed to correlate the airborne level of TEG, as established visually and subsequently measured through an optical particle sensor, to the mass of aerosol in the air. The study also aimed to determine whether, when the Grignard Pure level is held constant, if the correlation between particle

sensor readings and concentration changes over time. If the data demonstrate a linear relationship, then the measurements from a particle sensor can use used to determine the real time airborne concentration of TEG, and that these concentrations can be associated with visually observed levels of airborne Grignard Pure ranging from invisible to moderate haze.

- **Test Method #1**
    - Testing was conducted in a 1575 ft^3 (44.5 m^3) windowless room with dimensions 15' x 15' x 7' with approximately 3 air changes per hour.
    - Room was ventilated prior to use and in between each treatment level. Removal of residual product in the air was verified utilizing the DRX Aerosol Monitor.
    - Two small, portable Honeywell Home—Table circulation fans were strategically placed in the room to allow uniform dispersion of Grignard Pure. The fans were run continuously for the entire duration of the experiment at the highest output setting. A water-based haze machine was utilized to generate 5 different treatment levels of Grignard Pure. The haze machine was placed 4 feet above ground and 2 feet from the Grignard Poster. Temperature of the room was between 20°C - 23°C at relative humidity of 50 -55%.
    - Aerosol monitoring was conducted with the Handheld DustTrak DRX Aerosol Monitor 8534 (a multi-channel, battery operated, data-logging, light-scattering laser photometer that gives real-time aerosol particle counts and mass readings). The monitor was calibrated by the manufacturer according to ISO Standard 12103-1 A1 using ultrafine test dust. Prior to each test, the DRX 8534 was zeroed using the zero filter.
    - Air concentration levels of TEG were measured using the NIOSH Method 5523, where XAD-7 OVS sampling tubes were used as the collection media. The OVS tubes combine sorbent and filter into one glass tube to trap aerosols and vapors simultaneously. The sampling pumps were calibrated to 1.2 L/min flow rate using a calibrated rotameter.
    - The air pumps and sampling media were placed 5 feet above ground corresponding to the breathing zone for most people and 3 feet sideways from the haze machine to measure the concentration of TEG in the room. Blank samples were collected before the haze machine was turned on. The haze machine was turned on to reach a specific level of treatment and time was given to allow uniform dispersion through the room. Required level of treatment was confirmed when the visual observation matched the photographic image, and uniformity of dispersion was confirmed when the readings on the aerosol monitor were stable for at least one minute.
    - The GilAir 3 sampling pumps were turned on and the sample was collected for 4.16 minutes at a verified flow rate of 1.2 L/min for a total sample volume of 5 L. The room was ventilated between the different treatment levels tested. All collection sample media and blanks were stored in a thermal bag with cooler packs and sent to Analytics Corporation (an American Industrial Hygiene Association (AHA) accredited lab).
    - All samples were analyzed in accordance to the NIOSH 5523 method using Gas Chromatography – Flame Ionization Detection method.

The NIOSH method was extended to a validated Limit of Detection of 15.0 µg/L of TEG.

- The calibration curve generated shows positive correlation between the aerosol monitor and Analytics Laboratory measured TEG concentrations. Hence, an aerosol monitor can be utilized for a real time estimation of TEG concentration in the air at any Grignard Pure Treatment Level
- It should be noted, the aerosol monitor measures total Grignard Pure aerosol concentration whereas the NIOSH method utilized by the laboratory measures the total TEG concentration
- Overall, the Triethylene Glycol concentrations are expected to range from < 3.0 mg/m^3 to 5.18 mg/m^3 for the five different levels of Grignard Pure air treatment.

- **<u>Test Method #2</u>**
  - The setup of the chamber and equipment utilized for air sampling in this test remained the same as Test 1. For this test, the chamber was maintained at a very light haze level for 3 hours.
  - Visual observation matching the very light visibility level and concentration value reported by the aerosol monitor was monitored during the 3 hours to ensure a constant level of Grignard Pure. Once the intended haze level was attained and the aerosol monitor indicated uniform dispersal, the GilAir3 sampling pumps were turned on and the sample was collected for 4.16 minutes at a verified flow rate of 1.2 L/min for a total sample volume of 5 L at time zero, 15 minutes, 90 minutes, and 120 minutes.
  - Total TEG concentration when Grignard Pure treatment is maintained at a very light haze level for three hours remained < 3 mg/m^3.
  - While this is a good indication that maintaining a specific level of concentration will not increase the total TEG concentration over time, it cannot be determined whether the TEG concentration is maintained throughout the period of testing.
- Generating Calibration Factor
  - The total TEG concentration at each treatment level was reported by Analytics Corporation from their analysis of the samples. The average recorded concentration value on the Aerosol Monitor at each treatment level was plotted against the Laboratory measured concentrations and a linear regression model was used to show the relationship between the two concentration values. The slope of the curve was calculated to determine the calibration factor. The calibration factor turns real time aerosol concentration values to the TEG glycol concentrations for the Grignard Pure fluid.

$$CONC = C \times PDR$$

Where Conc = Total Concentration measured by Lab

C = Aerosol monitor calibration factor

  - As the Grignard Pure density increases in visual levels from a light treatment level to a moderate treatment level it is expected the concentration of TEG will subsequently increase. The Laboratory measured concentration was lower at the moderate treatment level compared to the light treatment level and hence was deemed an outlier. To determine a better correlation between the Aerosol monitor concentrations and the laboratory measured concentration, the moderate

treatment level, was removed from the calibration curve. The resulting calibration curve provides an extraordinarily good fit to the data. PDR = Real time aerosol concentration.

- Based on the known percentage of TEG in the Grignard Pure, the laboratory measured TEG concentrations are lower than expected. This discrepancy in the aerosol monitor values and the laboratory measured values can be attributed to the material utilized for calibration of the aerosol monitor. The aerosol monitor was calibrated to ISO 12101-A1 Arizona Test Dust that has an average density of 2.6 g/cm^3. Grignard Pure has a density of 1.08 g/cm^3 making it half the density of the Arizona Test Dust. Taking this into consideration, the laboratory measured concentrations are accurate when the aerosol monitor values are adjusted for the differences in density of the calibration material to the Grignard Pure measured product.

2. Presentation to the EPA, Connecting Air Concentrations to Efficacy and Safety Values, dated 12/9/2020

- Details 3 methods used to measure Grignard Pure and TEG Concentrations
  - Visual Assessment, Particle Sensors, and Chemical Analysis of Air Samples
- Linked Different Measurement Techniques
  - Microchem Study NG16240: Used visual assessment, particle sensor, and machine settings to determine the concentration of Grignard Pure when introduced into a chamber containing nebulized virus.
  - Grignard Pure NIOSH Air Sampling Triethylene Glycol Concentration in Air: Study used visual assessment, particle sensors, and a NIOSH-approved sampling and chemical analysis method simultaneously.
- Converting Sensor Measurements to Grignard Pure Measurements
  - The sensor is calibrated to ISO Standard 12103-A1 utilizing Ultrafine Arizona Road Dust
  - Arizona Road Dust has a density of 2.7 g/cm^3 while Grignard Pure has a density of 1.08 g/cm^3; difference is correction factor of 0.4
- Efficacy Testing, Microchem Study NG16240
  - The concentrations of Grignard Pure in Test #1 and Test #2 are the same because the equipment settings were identical.
  - In Test #2, the sensor readings are not a reliable indication of Grignard Pure levels because they measure both virus particles and Grignard Pure.
- TEG Concentrations, NIOSH Glycol Testing Methodology
  - Process
  - The average recorded concentration value of Grignard Pure from the particle sensors at each haze density was plotted against the laboratory measured concentrations of TEG, and a linear regression model was used to show the relationship between the two concentration values; the slope of the curve was calculated to determine the calibration factor.

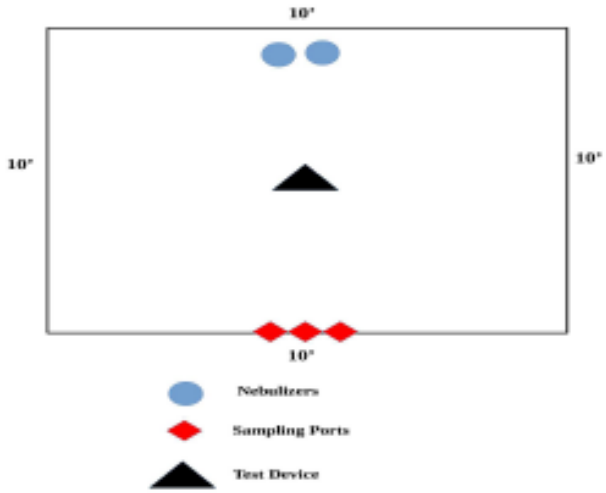
V TECHNICAL QUESTIONS AND APPLICANT RESPONSES TO ADDRESS EFFICACY ISSUES

GRIGNARD RESPONSES TO AGENCY'S INITIAL QUESTIONS (dated 10/6/2020)

Agency's Question: Can the air sampling rate/capacity for bacteriophage be provided so we can better to determine control and recovery?
Registrant's Response: The air sampling rate is 12.5 L/min.

Agency's Question: What is the location of the nebulizer relative to impinger(s)?
Registrant's Response: The nebulizers are located on the opposite side of the chamber ~10 feet away from the impingers.

Agency's Question: Is the sampling impinger activated when product is being nebulized? Where is the nebulizer placed in reference to the sampling procedure?
Registrant's Response: The air samples are taken after nebulization has completed. Nebulizers are run for 60 minutes. The nebulizers are placed on the opposite side of the room as the impingers (see diagram below).



Agency's Question/Comment: How was neutralization effectiveness conducted? The study references a suspension test. The neutralization process needs to be explained.
Registrant's Response:

- 1.0 ml of Test Substance was added to 9.0 ml of phosphate buffered saline (PBS) with 0.1% tween 80 in a 15 ml conical.
- A separate 15 ml conical is filled with PBS with 0.1% tween 80 and used as the control.
- Both tubes are inoculated with 10-100 PFU/ml of MS2 Bacteriophage ATCC 15597-B1.
- From each tube a 1.0 ml volume is plated to determine concentration.

Agency's Question: How is/are the collected sample(s) process after collecting in the impinger?
Registrant's Response:

- Once samples are collected, samplers are moved to a biological safety cabinet for processing.
- Each neck is rinsed with 5 ml of sterile phosphate buffered saline. This liquid is allowed to drain into the collection cup of the vessel.
- The liquid is transferred into a sterile 50 ml conical or equivalent sterile vessel. During the transfer, the total liquid volume is observed and recorded.
- The sampler liquid is then enumerated.

Agency's Question/Comment: It is unclear how log reductions were determined (i.e. reductions of microorganisms calculated relative to concentration at time zero or by way of corresponding control run sample). Can additional clarify be provided?
Registrant's Response:

The following are calculations used in the study:

PFU/ml = [(PFU on plate 1 + PFU on plate 2) / 2] * dilution factor PFU/m^3 = 1,000 * {[(PFU/ml) x V] / [T x 12.5]}
Where V is the total volume of recovery fluid in bio sampler
Where T is the total time in minutes the bio sampler drew an air sample

Log reduction = Log [(PFU/m^3 of time zero) / (PFU/m^3 of test)]
Adjusted Log Reduction = Log reduction of test – the log reduction of parallel baseline

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Agency's Question: Is the room conditioned (temperature/humidity) prior to testing? Is the room continuously conditioned (temperature/humidity)?
Registrant's Response: The chamber is a sealed room with no air conditioning. Study sponsor requested the humidity to be between 35% and 40% humidity. A dehumidifier was run if the chamber was above 40% humidity.

Agency's Question: What is the purpose of the 4 hours of UV exposure?
Registrant's Response: The UV light is run for 4 hours after the chamber runs have been completed to decontaminate the chamber prior to personnel re-entry into the chamber.

Agency's Question: Does the nebulizer operate continuously for 3 hours or is it restarted after each sampling event?
Registrant's Response: The microorganisms are nebulized for 60 minutes or until all the inoculum has been expelled. Once there is no more inoculum in the nebulizers, the air compressor that the nebulizers are connected to is shut off and nebulization is stopped. The time zero sample is then taken to determine the concentration of microorganisms present in the air inside the chamber.

Agency's Question: The baseline control counts at 2 hours were used to calculate the adjusted log reduction compared to baseline for 1.5 hours. Please provide justification for this comparison.

Registrant's Response: The 2-hour time point would be a worst-case scenario for natural die off and gravitational settling. Comparing the 1.5 hour to the 2 hours give a worst-case scenario of gravitational settling and die off to show the effectiveness of the test substance.

Agency's Comment: Please provide an explanation of the incubation time of 12-18 hours which seems quite short.
Registrant's Response: From internal validations 12-18 hours of incubation time has been determined to be the optimal length of time for the growth of the host microorganism to reach log phase and to see the plaques that have formed due to the bacteriophage infecting the host microorganism.

Agency's Comment: What was the purpose of the following test?

> "Per the study instruction, a second test with the Amhaze Stadium Haze Machine was performed. The device was set to 50% fan speed and 100% haze output and the manual button was held for ~5 seconds and a light to light-moderate haze was achieved prior to nebulization of test microorganism. The test microorganism was then nebulized while maintaining a light to light-moderate haze for 60 minutes. Air samples were then taken at 1 minute, 15 minutes, and 60 minutes after nebulization completion. Because the test substance was released prior to nebulization, a time zero was not taken and the nebulization of the test microorganism cannot be confirmed. Since a time zero was not taken log reduction calculations could not be made for this portion of the test."

Registrant's Response: The purpose of this study was to simulate real use conditions. The product would be applied to a space before it is occupied by people. When space is occupied and people speak, cough or sneeze, the virus is introduced to the Grignard Pure air treatment. This study would simulate how quickly the Grignard Pure would attack the virus and inactivate it in such a scenario.

Agency's Comment: Please explain the calculations for log reductions (included on the last page of the study)
Registrant's Response: The following are calculations used in the study.

PFU/ml = [(PFU on plate 1 + PFU on plate 2) / 2] * dilution factor PFU/m3 = 1,000 *
{[(PFU/ml) x V] / [T x 12.5]}
Where V is the total volume of recovery fluid in bio sampler
Where T is the total time in minutes the bio sampler drew an air sample

Log reduction = Log [(PFU/m3 of Time Zero) / (PFU/m3 of test)]
Adjusted Log Reduction = Log reduction of test – the log reduction of parallel baseline

The PFU/m^3 is determined using the equations listed above, the PFU/m^3 of the time zero sample is divided by the PFU/m^3 of the test sample at a given time point. The $\log_{10}$ of the product is then taken to determine the log reduction.

Since there was no Time Zero PFU for the virus particles in this study, an average of the initial concentrations of the virus particles in the treatment chamber was determined from previous runs conducted at Microchem. These values were used to calculate adjusted log reductions at treatment points and determine log reductions in the test chamber.

Agency's Question: Would the formulation as part of this study be considered a fog, mist, or vapor? This may trigger different PPE requirements.
Registrant's Response: This would be considered either a "mist" or a "fog." Devices that will introduce Grignard Pure to the space will either heat or compress the solution to aerosolize the fluid. When the aerosol enters the atmosphere, it forms either a "fog" (a thick cloud of tiny droplets) or a "mist" (a less dense cloud of droplets). The density or visual opacity of the aerosol will depend on the number and sizes of the droplets. While Grignard Pure can be aerosolized at varying densities ranging from "no visible haze" (NVH) to "heavy,"

Agency's Comment: Provide the dimensions of the treatment space.
Registrant's Response: 18'8.5" x 16'8" x 11'9" = ~104 m^3

Agency's Question: What is meant by INTERVAL set to 30 minutes and DURATION set to 5 seconds as it relates to the contact time of 3 hours?
Registrant's Response: The INTERVAL and DURATION were the settings for fogger remote given by the Sponsor for operation of the fogger. The machine tested was set to give an output every 30 minutes and for 5 seconds to maintain the specified visual level of Grignard Pure in the air. Product was applied with this setting during the period of the experiment, and efficacy was calculated at the 3-hour contact time.

Agency's Question: Is the Hurricane 1800 FLEX the recommended device?
Registrant's Response: No. The product may be applied via any water-based haze or fog machine.

Agency's Question: For larger treatment spaces, how will temperature and humidity be regulated?
Registrant's Response: Based on the testing conducted thus far, there was no indication that efficacy changed dramatically with changes in temperature and humidity. The studies performed have had temperatures ranging from 23°C - 26°C and relative humidity ranging from 30% - 67%. If needed, humidifiers and or dehumidifiers will be utilized to set the humidity levels. Similarly, temperature can be regulated.

Agency's Question: For this study, was the treatment space empty of obstacles to mimic those items that cannot be removed?
Registrant's Response: Aside from a metal cart with a diagram to help visualize the level of fog generated (which was located behind the fogger and carrier placements) only the fogger and the carries were present in the testing room during the fogging exposure.

Agency's Question: The control carriers were held covered. This may have falsely elevated counts for the 3-hour period. The study states that the control films were held at the same exposure time and temperature; but at what humidity?

Registrant's Response: Per the raw data, the virus controls were held at 26.95% relative humidity
Agency's Follow-Up Response: Humidity for testing ranged from 48.10%-54.38% for human adenovirus testing; for human coronavirus 45.03% -66.65%

Agency's Question: Why was the study revised (Revised Report Date: July 1, 2020)?
Registrant's Response: Per Sponsor request on 6/30/20, the 15-minute exposure information was removed from the previous report. Grignard can show results from 15 minutes. Grignard anticipated the product wouldn't have significant efficacy within 15 minutes but wanted to get a measurement of efficacy at 15 min to see how it compared to air inactivation. We determined it does not need to be included in the report because, as expected, it did not show a significant level of efficacy.
Agency's Follow-Up Response: Testing with MS2 demonstrated 2-3 log reduction.
Registrant's Final Response: Efficacy data for MS2 bacteriophage demonstrated efficacy at 15 minutes; discrepancy with the human viruses.

Agency's Question: How does one account for major differences in the amount of product used for priming and testing between the two carrier-based tests?
Registrant's Response: Water based haze and fog machines are usually primed with maintenance fluid. In order to ensure the product coming out of the delivery machine was Grignard Pure, the lab was instructed to manually operate the machine and allow Grignard Pure to run through the system for several minutes. The first test conducted was on the Human Coronavirus and since it was the first time for the lab running this machine, the reported amount of Grignard Pure utilized was higher than when the test was run later with the Human Adenovirus. This accounts for the differences in the priming weight. The concentration of Grignard Pure was to be the same for both the Adenovirus and Human Coronavirus tests. However, it is possible that, since the concentration in the test chamber was determined visually, there may have been a difference in how the concentration of the Grignard Pure was perceived. If so, there may also have been a difference in the manual output of the product to maintain the visible concentration at the moderate level. Thus, this factor may also account for some of the difference in amount of product utilized in both tests.

Agency's Comment: Virus input control was not included in the test summary. Please provide.
Registrant's Response: This is included on page 3 and page 6 of the report. The report states that it is for informational purposes only. If the intent of the question is for it to be included in the "Conclusion" section, that is something we have never done, not even in GLP reporting.

Agency's Comment: The log reduction should be based on the dried carrier control at 3-hour.
Registrant's Response: There are log reductions in the report based on the zero time and 3-hour virus control.

Agency's Comment: What are the required temperature ranges?
Registrant's Response: Product does not have a specific temperature range.

Agency's Comment: The control carriers were held covered. This may have falsely elevated counts for the 3-hour period. The study states that the control films were held at the same exposure time and temperature; but what at humidity?
Registrant's Response: Per the raw data, the virus controls were held at 20.18% relative humidity
Agency's Follow-Up Response Humidity for testing ranged from 48.10%-54.38% for human adenovirus testing; for human coronavirus 45.03% -66.65%

Agency's Comment: The log reduction should be based on the dried carrier control at 3-hour time period (1.84 not 3.32). Provide an explanation for why this was not the case.
Registrant's Response: Both reductions are included in the report (vs zero time and vs 3 hour), see pages 5 & 9.

GRIGNARD RESPONSES TO AGENCY'S QUESTIONS (dated 11/3/2020)

Agency's Question/Comment**: –** In the Section 18 application, the Rate of Application details the following

> The attached label contains detailed use direction on the rate of application of Grignard Pure product needed to treat an enclosed space. The amount will depend on the volume of the treated space and how long the treatment is conducted. The use directions instruct the user on how to estimate the volume of the space and provide a table that indicates the amount needed for different volumes. The use directions instruct the user to operate the machine until a moderate haze is achieved. The use directions refer the user to a chart displaying pictures that show how to determine when the appropriate haze density is reached.

This information is not included on the Grignard Pure Gallon Wrap Label.

Registrant's Response: Grignard has revised the label (see attachment A) to address this error. Grignard acknowledges that the previously submitted label does not have a table showing how much Grignard Pure would be used to treat indoor spaces of varying sizes. As noted on that label, the amount of product needed to treat a space will vary depending on multiple, site-specific factors including, primarily, the volume of air treated, the duration of the treatment, and the rate of introduction of outside air, and to a lesser extent, the number of air changes per hour. Because the application quantity will vary due to these factors, the current label directions deletes the third sentence of this paragraph of text.

Agency's Question/Comment**:** In the Section 18 application, the Method of application section details the following:

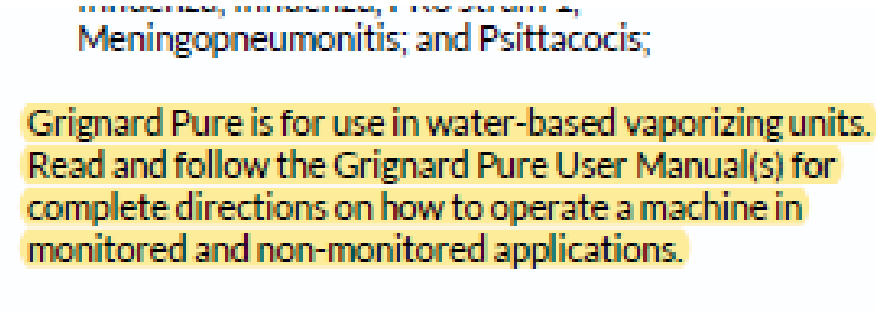
Grignard Pure is for indoor use in fog/haze machines widely used in the lighting industry or in smoke simulator machines. The label provides detailed use directions on how to place machines and to operate the machines to achieve and maintain a moderate haze level. The use directions describe two different ways to deploying the haze—through an HVAC system and by placing the machine(s) in the enclosed spaces being treated. Directions for Use in the proposed label for information concerning concentration and standard machine use or at an HVAC central return plenum, or application via HVAC system distribution.

Information pertaining to machines set-up, fan(s) placement, and room preparation are not included on the proposed label. Further, none of the submitted efficacy studies include the HVAC unit as a method of product distribution.

Registrant's Response: The label indicates that application equipment and (when used) any sensors are to be placed under the direction of a Grignard-certified installer. These installers will have the professional qualifications to determine what kinds of equipment are best suited to treat a particular indoor space and where the equipment should be placed. The installer will be qualified to the use of equipment to disperse Grignard Pure through an HVAC system. The label does not include instructions regarding the use of fans or room preparation because the engineering studies performed with Grignard Pure have confirmed that supplemental fans are not needed, and no special preparations are needed for the indoor space when the product is introduced through and HVAC system. The certified installer will determine whether the use of supplemental fans is necessary when free standing machines are used.

While the efficacy studies have not been performed using an HVAC system, engineering studies have determined that Grignard Pure can be delivered into an indoor space at concentrations matching those used in efficacy studies. Grignard Company thinks that the product will be efficacious when it is at the proper concentration in the air, regardless of whether that concentration is achieved by free-standing equipment or an HVAC system.

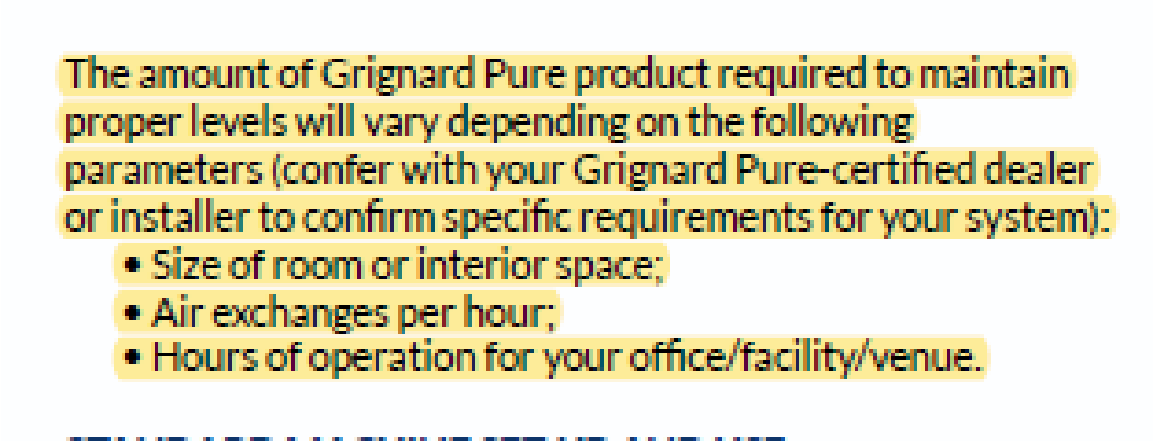
Agency's Question/Comment**:** The provided label references user manuals (screenshot below); none of which have been provided.


Meningopneumonitis; and Psittacocis;

Grignard Pure is for use in water-based vaporizing units. Read and follow the Grignard Pure User Manual(s) for complete directions on how to operate a machine in monitored and non-monitored applications.

Registrant's Response: The Grignard Pure website provides an initial list of certified air treatment machines and copies of their operating manuals.

Agency's Question/Comment**:** The proposed label includes the following statement:

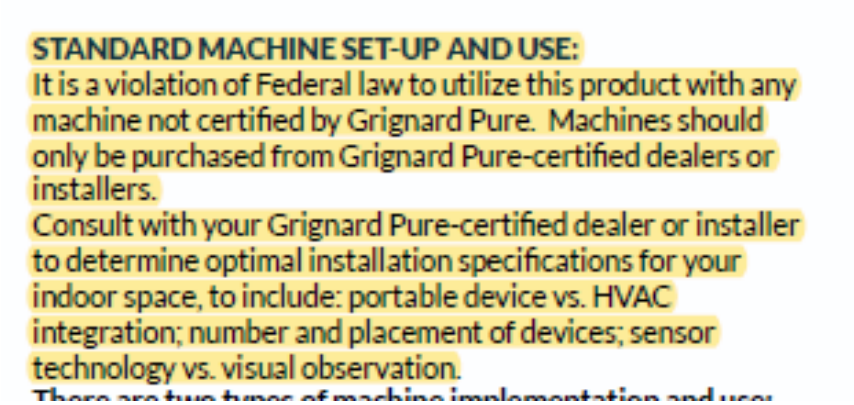

The amount of Grignard Pure product required to maintain proper levels will vary depending on the following parameters (confer with your Grignard Pure-certified dealer or installer to confirm specific requirements for your system):

- Size of room or interior space;
- Air exchanges per hour;
- Hours of operation for your office/facility/venue.

This information of proper usage should be included on the label as stated in the Section 18 application, Rate of Application.

Registrant's Response: Given the different methods of application and the multiple conditions that affect the amount of material needed, it is not possible to write use directions in the manner commonly used for agriculture or other antimicrobial pesticides. Instead, the proposed label indicates that the user will be responsible for operating the equipment in a manner that produces the proper concentration of Grignard Pure in the air. The label provides clear instructions for the user about how determine air levels of Grignard Pure. These instructions describe two approaches: the use of sensors and visual assessment, each of which should be adequate to ensure that the level of Grignard Pure in the air will be safe and efficacious.

Agency's Question/Comment: The proposed label includes the following statements regarding machine placement, number of machines to use, integration into the HVAC system, and utilization of sensors:



STANDARD MACHINE SET-UP AND USE:
It is a violation of Federal law to utilize this product with any machine not certified by Grignard Pure. Machines should only be purchased from Grignard Pure-certified dealers or installers.
Consult with your Grignard Pure-certified dealer or installer to determine optimal installation specifications for your indoor space, to include: portable device vs. HVAC integration; number and placement of devices; sensor technology vs. visual observation.
There are two types of machine implementation and use:

None of this information was adequately fleshed out in the information provided (Section 18 or proposed label; user manuals have not been provided). Additional information is required for the sensors. Where are they placed? How are they monitored? What is the targeted product range based on the submitted efficacy data?

Registrant's Response:

Sensor Placement: The sensors realize automatic measurement of the concentration of particles in the air and act to maintain the efficacy concentration level of the Grignard Pure product, i.e. 0.5 to 3.0 mg/m^3. Placement of sensors is integral to maintain the efficacy of Grignard Pure. For an HVAC system, the first sensor is placed where the greatest concentration of Grignard Pure is delivered to a space (usually near the first air duct register off of the HVAC system). While observing the natural air flow in the rest of the space the other sensors [typically two) are split evenly apart to cover at least 80% of the remaining space. If space is large, more sensors are used up to a maximum of ten and placed into equidistant quadrants within the space. If needed, we can provide a recommended sensor count per cubic feet of treated space.

Sensor Monitoring: The sensors provide a signal to a controller, which has a centralized processor (SMU}, that records concentration levels measured by each system sensor. Sensors have a mandatory check in time. If a sensor does not report after several retries, it will go into the faulty list and an optional email can be sent to the subscriber or site representative. The SMU records the data in a local database on the SMU. The SMU has a publish/subscribe messaging system. Whenever pertinent data is entered into the SMU database, all subscribed systems instantly receive that message via a dedicated, cloud-based server. When the cloud-based server receives the message and stores that data in its database, it is available to subscribed users for their use in a graphical user interface (GUI) display. Alarm and level indicators are monitored by the GP certified service provider or by using the local user's environmental control system, such as BACnet.

These principles will be incorporated into the training program for Grignard Pure certified installers.

Agency's Question/Comment: The Section 18 application states moderate haze should be achieved, while the proposed label recommends a very light haze and a moderate haze (0.5 mg/m^3 to 2 mg/m^3).

Registrant's Response: The targeted range of airborne concentrations of Grignard Pure stated on the current label (Attachment A), 0.5 mg/m^3 to 3 mg/m^3, is correct. Grignard notes that the application was prepared before testing showed that the product displayed significant efficacy at lower concentrations than was used in the initial round of efficacy studies. Because potential users think there will be greater consumer acceptance of the air treatment if it has a lower density, the label's use directions reflect the intended use of a lower airborne concentration of Grignard Pure.

Agency's Question/Comment: Again, the user manual (not provided) is referenced as a resource for illustrating the proper density of haze. **Table 1** below refers to the amount of product used in the submitted efficacy studies. What is the correlation between the amount tested and the suggested density to be achieved/maintained?

Registrant's Response: The studies in Table 1 were conducted at a moderate haze level which is higher than the density levels specified on the current Grignard Pure label.

Agency's Question/Comment: How do the varying tested amounts translate into the amounts to the label instructions and an earlier response to use a non-visible to light haze?

Registrant's Response: The amount of Grignard Pure to be utilized at a non-visible to light haze is achieved at concentration levels of 0.5 – 3mg/m^3

Agency's Initial Question: Can the air sampling rate/capacity for bacteriophage be provided so we can better to determine control and recovery?

Registrant's Response: The air sampling rate is 12.5 L/min.

Agency's Follow-Up Question: What is the total time in minutes the bio sampler drew in an air sample at each contact time? Is it the same ten-minute sampling time used to establish the time zero?

Registrant's Final Response: The bio samplers were run for 10 minutes for each contact time

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Agency's Initial Question/Comment: It is unclear how log reductions were determined (i.e. reductions of microorganisms calculated relative to concentration at time zero or by way of corresponding control run sample). Can additional clarify be provided?

Registrant's Response:

The following are calculations used in the study:

PFU/ml = [(PFU on plate 1 + PFU on plate 2) / 2] * dilution factor PFU/m^3 = 1,000 * {[(PFU/ml) x V] / [T x 12.5]}

Where V is the total volume of recovery fluid in bio sampler
Where T is the total time in minutes the bio sampler drew an air sample

Log reduction = Log [(PFU/m^3 of time zero) / (PFU/m^3 of test)]

Adjusted Log Reduction = Log reduction of test – the log reduction of parallel baseline

Agency's Follow-Up Question (duplicate from above): What is the total time in minutes the bio sampler drew in an air sample at each contact time? Is it the same ten-minute sampling time used to establish the time zero?

Registrant's Response: The bio samplers were run for 10 minutes for each contact time

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Agency's Initial Question: Is the room conditioned (temperature/humidity) prior to testing? Is the room continuously conditioned (temperature/humidity)?

Registrant's Response: The chamber is a sealed room with no air conditioning. Study sponsor requested the humidity to be between 35% and 40% humidity. A dehumidifier was run if the chamber was above 40% humidity.

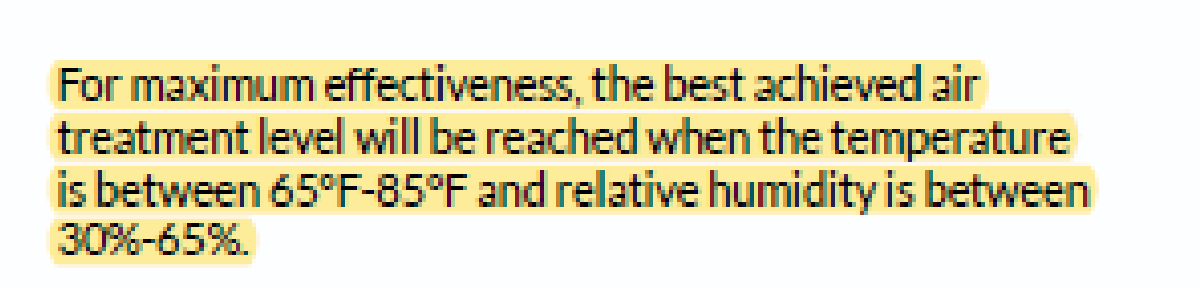
Agency's Follow-Up Response: Temperature/humidity were not regulated, just recorded for the carrier-based studies. The proposed label includes this recommendation for maximum effectiveness.

Registrant's Final Response: Temperature and RH conditions were provided to the labs and maintained for the baseline as well as control studies. As shown in Table 2, studies conducted at Microchem, maintained RH between 35% - 40% and temperature between 24°C – 26°C. Studies conducted at ALG, maintained RH between 45% - 66% and temperature between 23°C – 26°C. The label recommendation for control of temperature and relative humidity is consistent with the conditions under which testing was conducted on efficacy of Grignard Pure.

Most commercial buildings are able to maintain a temperature within a range of 65°F – 80°F and a relative humidity range between 25% and 60%. In order for GP to be available in as many indoor spaces as it would be useful, the label specifies ranges that are broader than have actually been tested. Grignard thinks that the product will still provide significant efficacy when used within these ranges. This conclusion rests on data which shows TEG is more effective at higher temperatures and that the changes in relative humidity do not significantly affect efficacy.

Agency's Comment/Question: In an earlier response, the registrant stated the following

Based on the testing conducted thus far, there was no indication that efficacy changed dramatically with changes in temperature and humidity. The studies performed have had temperatures ranging from 23°C - 26°C and relative humidity ranging from 30% - 67%. If needed, humidifiers and/or dehumidifiers will be utilized to set the humidity levels. Similarly, temperature can be regulated.



The temperature range (65°F - 85°F) proposed on the label has not been justified with efficacy data.

Table 2. Comparison of Temperature and Humidity Testing Conditions

Study	Temperature	Humidity
1. Evaluation of Bioaerosols and Grignard's Test Substance NG15232	Not recorded	Not recorded
2. Evaluation of Bioaerosols and Grignard's Test Substance NG15621	Base Line: 25.4°C/24.9°C	Base Line: 35% /37%
	Amhaze: 24.8°C/24.8°C	Amhaze: 33%/ 33%
3. Evaluation of Bioaerosols and Grignard's Test Substance NG15621	Base Line: 25.4°C/ 24.9°C	Base Line: 35% /37%
	Hurricane: 25.1°C/25.1°C	Amhaze: 37% /37%
4. Evaluation of Bioaerosols and Grignard's Test Substance NG15621	25.1°C/ 25.3°C	38% /35%
5. Virucidal Efficacy of a Disinfectant Applied to a Room Via a Fogging, Misting or Vaporizing Device, Study conducted by Analytical Lab Group (ALG), #GRI002040820.COR	24.7°C/23.5°C	45.03%/66.65%

6. Virucidal Efficacy of a Disinfectant Applied to a Room Via a Fogging, Misting or Vaporizing Device, Study conducted by Analytical Lab Group (ALG), #GRI002040820.ADV	24.73°C / 23.75°C	54.38% / 48.10%

Registrant's Response: Temperature and RH conditions were provided to the labs and maintained for the baseline as well as control studies. As shown in Table 2, studies conducted at Microchem, maintained RH between 35% - 40% and temperature between 24°C – 26°C. Studies conducted at ALG, maintained RH between 45% - 66% and temperature between 23°C – 26°C. The label recommendation for control of temperature and relative humidity is consistent with the conditions under which testing was conducted on efficacy of Grignard Pure.

Most commercial buildings are able to maintain a temperature within a range of 65°F – 80°F and a relative humidity range between 25% and 60%. In order for GP to be available in as many indoor spaces as it would be useful, the label specifies ranges that are broader than have actually been tested. Grignard thinks that the product will still provide significant efficacy when used within these ranges. This conclusion rests on data which shows TEG is more effective at higher temperatures and that the changes in relative humidity do not significantly affect efficacy.

Agency's Initial Question: Would the formulation as part of this study be considered a fog, mist, or vapor? This may trigger different PPE requirements.

Registrant's Response: This would be considered either a "mist" or a "fog." Devices that will introduce Grignard Pure to the space will either heat or compress the solution to aerosolize the fluid. When the aerosol enters the atmosphere, it forms either a "fog" (a thick cloud of tiny droplets) or a "mist" (a less dense cloud of droplets). The density or visual opacity of the aerosol will depend on the number and sizes of the droplets. While Grignard Pure can be aerosolized at varying densities ranging from "no visible haze" (NVH) to "heavy,"

Agency's Follow-Up Response: The qualitative instructions stated above "at least an NVH and no more than a "very light haze do not provide much information regarding the actual targeted amount, and these instructions are inconsistent with Section 18 Method of Application section. The studies do not provide much insight on the actual amount to be used.

Registrant's Final Response:

Sensor Placement: The sensors realize automatic measurement of the concentration of particles in the air and act to maintain the efficacy concentration level of the Grignard Pure product, i.e. 0.5 to 3.0 mg/m^3. Placement of sensors is integral to maintain the efficacy of Grignard Pure. For an HVAC system, the first sensor is placed where the

greatest concentration of Grignard Pure is delivered to a space (usually near the first air duct register off of the HVAC system). While observing the natural air flow in the rest of the space the other sensors [typically two) are split evenly apart to cover at least 80% of the remaining space. If space is large, more sensors are used up to a maximum of ten and placed into equidistant quadrants within the space. If needed, we can provide a recommended sensor count per cubic feet of treated space.

Sensor Monitoring: The sensors provide a signal to a controller, which has a centralized processor (SMU}, that records concentration levels measured by each system sensor. Sensors have a mandatory check in time. If a sensor does not report after several retries, it will go into the faulty list and an optional email can be sent to the subscriber or site representative. The SMU records the data in a local database on the SMU. The SMU has a publish/subscribe messaging system. Whenever pertinent data is entered into the SMU database, all subscribed systems instantly receive that message via a dedicated, cloud-based server. When the cloud-based server receives the message and stores that data in its database, it is available to subscribed users for their use in a graphical user interface (GUI) display. Alarm and level indicators are monitored by the GP certified service provider or by using the local user's environmental control system, such as BACnet.

These principles will be incorporated into the training program for Grignard Pure certified installers.

Agency's Comment: Provide the dimensions of the treatment space.

Registrant's Response: 18'8.5" x 16'8" x 11'9" = ~104 m^3

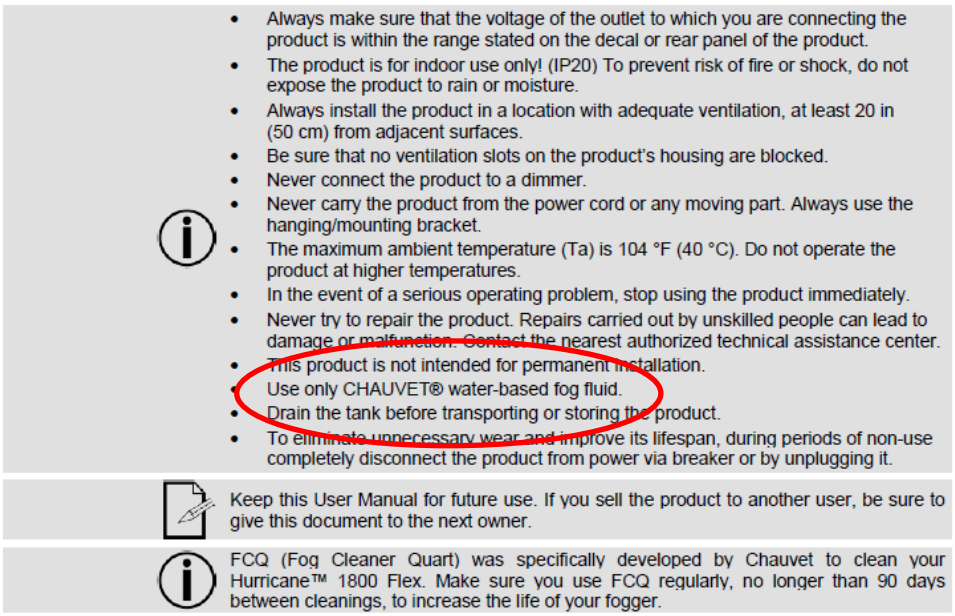
Agency's Follow-Up Response: Will the label reflect same information/limitations of specified/possible use locations representative of these specification? There should be limitations to the treatment space/or requirement to increase the number of units/fans, etc.

Registrant's Response: The label indicates that application equipment and (when used) any sensors are to be placed under the direction of a Grignard-certified installer. These installers will have the professional qualifications to determine what kinds of equipment are best suited to treat a particular indoor space and where the equipment should be placed. The installer will be qualified to the use of equipment to disperse Grignard Pure through an HVAC system. The label does not include instructions regarding the use of fans or room preparation because the engineering studies performed with Grignard Pure have confirmed that supplemental fans are not needed, and no special preparations are needed for the indoor space when the product is introduced through and HVAC system. The certified installer will determine whether the use of supplemental fans is necessary when free standing machines are used.

While the efficacy studies have not been performed using an HVAC system, engineering studies have determined that Grignard Pure can be delivered into an indoor space at concentrations matching those used in efficacy studies. Grignard Company thinks that the product will be efficacious when it is at the proper concentration in the air, regardless

of whether that concentration is achieved by free-standing equipment or an HVAC system.

Agency's Question: The User Manual for the Chauvet machine requires the use of a water- based fog fluid only (Premium Haze Fluid (PHF). While the User Manual for the Hurricane 1800 FLEX includes the following (see excerpt (red circle) from the User Manual):



- Always make sure that the voltage of the outlet to which you are connecting the product is within the range stated on the decal or rear panel of the product.
- The product is for indoor use only! (IP20) To prevent risk of fire or shock, do not expose the product to rain or moisture.
- Always install the product in a location with adequate ventilation, at least 20 in (50 cm) from adjacent surfaces.
- Be sure that no ventilation slots on the product's housing are blocked.
- Never connect the product to a dimmer.
- Never carry the product from the power cord or any moving part. Always use the hanging/mounting bracket.
- The maximum ambient temperature (Ta) is 104 °F (40 °C). Do not operate the product at higher temperatures.
- In the event of a serious operating problem, stop using the product immediately.
- Never try to repair the product. Repairs carried out by unskilled people can lead to damage or malfunction. Contact the nearest authorized technical assistance center.
- This product is not intended for permanent installation.
- Use only CHAUVET® water-based fog fluid.
- Drain the tank before transporting or storing the product.
- To eliminate unnecessary wear and improve its lifespan, during periods of non-use completely disconnect the product from power via breaker or by unplugging it.

Keep this User Manual for future use. If you sell the product to another user, be sure to give this document to the next owner.

FCQ (Fog Cleaner Quart) was specifically developed by Chauvet to clean your Hurricane™ 1800 Flex. Make sure you use FCQ regularly, no longer than 90 days between cleanings, to increase the life of your fogger.

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Further, the User Manual for the Hurricane 1800 Flex states that no other product can be used in the machine

Registrant's Response: Grignard will work with Chauvet and other GP certified equipment manufacturers to revise the User Manual so it is clear that Grignard Pure may be used in the machines.

Agency's Comment/Question: Does the haze machine run continuously (decontamination) for 3 hours or is it restarted after each sampling event?

Registrant's Response: According to the proposed label, the air treatment machine can be operated continuously for up to 12 hours. When sensors are used, they will provide a continual, real time measurement of the level of Grignard Pure in the air and will be

connected to the air treatment machine in a way that ensures it operates to maintain the intended airborne concentration.

Agency's Question/Comment: Food preparation areas/food processing facilities should be limited to non-food contact.

Registrant's Response: As explained in Grignard's earlier responses, this restriction appears unnecessary in light of the existing and proposed tolerance exemptions for the ingredients in Grignard Pure. Reports investigating incidents of transmission often link the episodes to gatherings where people are preparing or consuming food.

Agency's Comment: Healthcare facilities should be limited to non-critical areas.

Registrant's Response: Grignard will revise the label to exclude use in the following critical health care areas: Emergency Room; Operating Rooms; Intensive Care Units.

Agency's Question/Comment: What is a Grignard Pure registered machine? How does it differ from the Amhaze and Hurricane 1800FLEX?

Registrant's Response: The label will require the use of "Grignard Pure certified equipment," a term that refers to a system of haze and fog machines, controllers, and sensors identified by Grignard Pure LLC as satisfying certain functional performance criteria. Specifically, a system must be capable of maintaining a minimum level of GP concentration to ensure efficacy, i.e. 0.5 mg GP/m^3 and controlling the amount of product released into an indoor space so that the concentration of Grignard Pure does not exceed a maximum level, i.e., 3 mg/m^3, for a continuous period of 12 hours. The label will include a direction to a website maintained by Grignard Pure LLC that identifies systems which the company has found to meet the specifications. The systems would include the Amhaze Stadium and Hurrican1800Flex.

Agency's Comment: There should be standard language for required signage when product is in use.

Registrant's Response: Grignard will revise the label to require (as opposed to recommending) posting of signs when product is in use.

Agency's Comment: Log reductions should be calculated utilizing a control for the same contact period. Utilizing control carriers generated immediately after inoculation for

any time period will falsely exaggerate the log reduction (where B= number of viable test microorganisms on the control carriers immediately after inoculation in the log reduction calculation and percent reduction calculation). This may be less of an issue for the 10-minute contact time, but why aren't dried carriers used to account for natural die off following drying? For the study identified as NG15621, B is identified as the number of viable test microorganisms at time zero after nebulization; this is significantly different from "B" for this study. Please explain why the log reduction calculations considered a different interpretation factor for B.

Registrant's Response: Grignard has provided EPA with the reports prepared by the private testing facilities. The laboratories have informed us that they prepared the reports following their internal Standard Operating Procedures. Grignard agrees that the calculation of the efficacy of Grignard Pure in reducing virus levels should account for the natural die-off and settling [NDOS] of virus particles over time after the completion of the nebulization of the inoculum. Measurements of virus levels after time zero will reflect both the antimicrobial activity of Grignard Pure and the NDOS of virus particles. Since the label's efficacy claim for Grignard Pure is based on sampling that began at 30 seconds and 3 minutes after introduction of Grignard Pure, the contribution of NDOS to any observed reduction in the levels of virus particles will be small. Moreover, the impact of NDOS can be calculated by applying the percentage reduction seen in the control chamber tests to the starting concentration in the test chamber. Any greater reduction would be due to the antimicrobial efficacy of Grignard Pure. (Further, Grignard has also developed an approach that accounts for the impact of NDOS on the apparent efficacy of Grignard Pure, based on additional measurements taken after longer periods.)

Agency's Comment: Language should be included that the use of this product does not replaced standard infection control procedures

Registrant's Response: Grignard agrees and will add this language to the Use Directions.

Agency's Comment: The Section 18 application review is limited to the requested microorganism. Claims for additional bacteria and viruses will not be considered for this Section 18.

Registrant's Response: Grignard will revise the label claims to delete references to bacteria and to any viruses other than SARS-CoV-2 and the influenza virus.

GRIGNARD RESPONSES TO AGENCY'S QUESTIONS (dated 11/25/2020)

Agency's Question/Comment: Please reference the evidence-based data to support the proposed use rate of 0.3 mg/m^3 - 5.0 mg/m^3**?** The efficacy studies provided thus far to AD fail to translate the haze densities to actual use rates/concentrations. The studies

provided to AD include haze densities from light to light moderate (non-visible densities were not included) with no reference to use rates/concentrations. One study (NG16240), does include use rates (referred to as "mass concentration total in mg/m^3" in this study) for non-visible to very light haze. Though provided in this study, the use rates ("mass concentration total in mg/m^3") appear to be higher than what is proposed on the label/application. I understand that this amount is room specific, but the study lacks the specifications of the treatment chamber. Resolution of this issue is critically important to understand how the haze densities translate into the proposed use rates. Of note, the efficacy study provided in the most recent version of the application, "Microchem_Custom Aerosol Study Report NG 15621 _ A1 (3 minute -light Haze" (page 31), is a duplicate of an initially submitted study. Lastly, based on the studies provided, what contact time is being proposed?

Registrant's Response: Microchem has conducted three studies of the efficacy of Grignard Pure [GP]. These studies have been conducted using different "haze densities," specifically study NG15232 at moderate haze level, study NG15621 at light – light moderate haze and study NG16240 at a non-visible haze and a very light haze. Microchem determined the haze density for each study, except study NG16240, by using the visual assessment method developed by the Grignard Company. For the NG16240 study, Microchem used a particle sensor to determine the operating parameters of the dispersion equipment that would produce the intended haze density / air concentration of GP. The explanation below will show how the haze density assessments by Microchem can be translated into air concentrations of Grignard Pure and its active ingredient, triethylene glycol [TEG]:

A. Grignard conducted a study to associate visually assessed haze densities with measurements of airborne concentrations of GP and TEG. (See Attachment A, Grignard Pure NIOSH Air Sampling Triethylene Glycol Concentration in the Air). Using the photographs on the label initially submitted to EPA (now to be included in the training materials for users), haze densities were assessed visually and photographed. Grignard then used two methods, a particle sensor and an air sampling device, to measure the airborne concentrations of GP and TEG, respectively, at three different density levels:

a. A particle sensor uses a light-scattering laser photometer to count aerosol droplets in different size ranges. The sensor then uses these measurements to calculate the total mass of all of the droplets in a specific volume of air. The sensor is calibrated to ISO Standard 12103-1 A1 utilizing "Ultrafine Arizona Road dust." Hence, when measuring airborne concentrations of any material other than Arizona Road Dust, a calibration factor has to be applied. Arizona Road dust has a density of 2.7g/cm^3 while Grignard Pure has a density of 1.08g/cm^3, and hence a correction factor of 0.4 would have to be applied to the particle sensor readings. Thus, as an example, for a particle sensor reading of 2mg/m^3, the GP concentration in the air would be 0.8mg/m^3 (0.4x 2mg/m^3)
b. A NIOSH air sampling method measures the concentration of TEG in an air sample. The average recorded concentration value of GP from the particle sensor at each haze density was plotted against the laboratory measured concentrations of TEG, and a linear regression model was used to show the relationship between the two

concentration values. The slope of the curve was calculated to determine the calibration factor. The calibration factor turns real time sensor measurements of the concentration of GP into the TEG concentrations. A calibration factor of 0.25 was calculated (See Figure 3, Attachment A). Thus, for a particle sensor reading of 2mg/m^3, the TEG concentration would be 0.5mg/m^3 (0.25 x 2mg/m^3). Not surprisingly, given that TEG is slightly more than half of the concentration of the GP fluid, the correlation factor for factor for TEG is a bit more than half of the correlation factor for GP, 0.4.

B. In step 1 of study NG16240, Microchem lab used a particle sensor to measure the airborne concentration of GP alone in its test chamber at given machine settings. Microchem informed us the chamber was dosed every 10 minutes for 10 seconds with a fan setting of 100% and product output setting of 7.8% on the Amhaze Stadium machine. At these settings, the dispersion equipment produced a concentration reading of 2 – 4mg/m^3 (0.8 – 1.6mg/m^3 real time GP concentration [0.5 – 1.0 mg/m^3 real time TEG concentration]) for a non-visible haze (NVH). Concentration of Grignard Pure in the chamber was recorded at each sampling point during the study (See table on page 15 of study NG16240). The average concentration for the non-visible haze for the duration of the experiment was reported at 4.16mg/m^3 (1.66mg/m^3 real time GP concentration).

C. In step 2 of study NG16240, Microchem lab ran the Amhaze Stadium machine at same settings described above in a separate chamber run with the virus present to determine the efficacy of GP against airborne virus particles. The concentration levels in the chamber were measured with the TSI 8534 and Extech VPC300 (See table on page 13 of study NG16240). (Please note that the concentrations reported in the tables on page 13 of study NG16240 are measurements for both the virus and GP and do not reflect any calibration factors to account for the difference in density between Arizona road dust and the material in the test chamber.)

D. Grignard has also run studies in house to generate visual density charts at specified machine settings. (See Attachment B, Grignard Pure Visual Density Chart). Grignard provided these settings as part of the protocol for study NG15621 and NG15232. Microchem independently verified that the given machine settings yielded the intended visual density of haze in the chamber (i.e. moderate haze and light – light moderate haze).

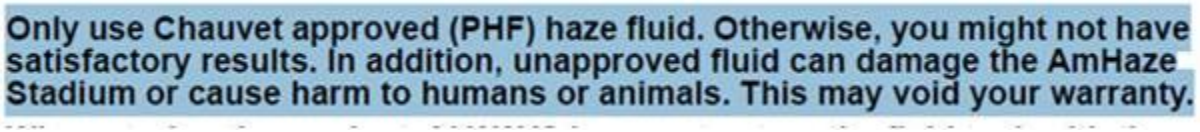
These studies show how it is possible to connect the efficacy results to a specific airborne concentration, when either estimated by visual assessment or measured by a particle sensor. Grignard NIOSH Study (Attachment A) shows that a particle sensor is a reliable way of measuring airborne concentration of GP as the NIOSH method that measures TEG. The study also shows that GP concentration can be connected to a visual assessment of haze density and to particle sensor measurements. Study B shows that machine settings can be connected to particle sensor measurements. Study C shows that machine settings and particle sensor readings can be connected to efficacy of Grignard Pure. Study D shows that visually assessing the density of the haze is a valid way to estimate the approximate concentration of GP in the air. Thus, we think that a visual assessment can be linked to both an efficacy result and an airborne concentration of GP.

We think these studies, taken together, have two additional benefits:

i. Making the use of aerosol monitors to measure the concentration, a valid way for users to know they are putting enough GP into the air to achieve a concentration that effectively reduces the level of airborne virus particles; and
ii. Making the use of visual observations another valid way for users to know they are putting enough GP into the air to achieve a concentration that will effectively reduce level of airborne virus particles. This shows the relevance of the initial Microchem efficacy studies in which the lab used a visual assessment to estimate the amount of GP needed.

Finally, we also note that, since the Microchem study NG16240 shows an NVH of GP is efficacious, it is reasonable to conclude that GP at a higher haze density, i.e., a higher concentration of GP, will provide greater efficacy than an NVH.

Agency's Comments/Question: What is the Grignard-certified dispersion unit revised user manual? The manuals for the two units used to generate efficacy data, Hurricane 1800 Flex Machine and the Amhaze Stadium Haze Machine (both manufactured by Chauvet), include the requirement for the use of Chauvet water-based fluid ONLY. Further, the Amhaze Stadium Haze Machine includes this statement:



Registrant's Response: Grignard has worked with Chauvet to revise user manuals to clarify that these user manuals are to be followed when using Grignard Pure. Please note these machines have been using the Chauvet PHF (haze fluid) which is very close in composition to Grignard Pure. The manuals are available for inspection on the Grignard Pure website, accessible via the directions below.

To access the currently Password Protected" section of the Grignard Pure site:

1.) Go to: grignardpure.com/my-account/

2.) Click on the "Customers" Tab -> "Registration / Log in"

3.) On the Register and Log In screen:
In the Log In section, enter the following:
Username: Magdil
Password: Magdil1

Click "Log In"

4.) You now have access to the currently password-protected area of the site, which includes:

Equipment / User Manuals: Here you have Product Name, Photo and User Manuals for both types of Installation:

- Wireless Installations
  - Dispersion Units
    - Model photos
    - Model user manuals
  - Sensor Kit
    - Item photos (Sensor/Controller/SMU unit)
    - User Manual
    - Installation Manual
- Hardwire Installations
  - Product photos:
    - Atomizer
    - Controller
    - Sensor
  - Installation /User Manual

Please note: the site is a work-in-progress and is continually being updated and enhanced in advance of launch and product availability and implementation.

Details of the Installer and end-user Qualification Programs

Grignard is currently working through the details of its training programs. Information about the planned requirements for training of installers and users is available on the Grignard Pure website, accessible via the directions below.

To access the currently Password Protected" section of the Grignard Pure site:

1.) Go to: grignardpure.com/my-account/

2.) Click on the "Customers" Tab -> "Registration / Log in"

3.) On the Register and Log In screen:
In the Log In section, enter the following:
Username: Magdil
Password: Magdil1

Click "Log In"

4.) You now have access to the currently password-protected area of the site, which includes:

Certifications: which outlines the two (2) Levels of Certification

Training: which currently acts as a placeholder, to indicate that when we have selected a training partner, this page is where people will go to access the online webinar and manual training tools

VI AGENCY'S FINDINGS AND CONCLUSIONS

1. The efficacy data provided to support the use of Grignard Pure as an air sanitizer against SARS-CoV-2 are acceptable at the use rates of 1.66 to 9 mg/m^3 (TEG equivalent concentration of 1.04 – 5.62 mg/m^3) for 12-hours of continuous operation at a temperature of 65-85°F at relative humidity of 25%-60%. Proper monitoring by visual observation and sensor monitoring (as specified on the label) is required to ensure that the use rates are consistently maintained. Note that the approval of the Section 18 is not a substitute for review of the full set of data needed to support a Section 3 registration, including appropriate number of lots, additional microorganisms needed to support the claim, adherence to approved methodologies and accepted performance standards.

2. The following items should be corrected as indicated in the user manuals.

Renew™ Air Treatment Solution, Version 1.0

- On page 6, change "dispersied" to "dispersed"
- On page 6, change "difraction" to "diffraction"

Appendix A. FIFRA SECTION 18 PUBLIC HEALTH EXEMPTION APPLICATION SYNOPSIS

Information detailed below was extracted from the Section 18 application (dated 11/17/2020).

Description of Pesticide

Trade Name: Grignard Pure

Active Ingredient(s): Triethylene Glycol (TEG)

Formulation: Provided on EPA Form 8570-4, Confidential Statement of Formula (CSF);

Manufacturer: Grignard Company, LLC

Federally Registered Product: Grignard Pure is not yet registered by the U.S. Environmental Protection Agency, Tennessee or Georgia.

Unregistered Product/New Chemical: Provided on EPA Form 8570-4, Confidential Statement of Formula (CSF);

Provisions for Return of Unused Product (unused product after expiration)

- See proposed label
    - Shelf life: The product is stable in an unopened container
    - Pesticide Disposal: Follow federal, state, and local government requirements for waste. Do not contaminate water, food, or feed by storage or disposal.
    - Container Disposal: Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by incineration.

Description of Product Use

Sites to be treated:

- Only for use in indoor occupied spaces including:
    - Health care facilities (e.g. hospitals, nursing homes, medical offices, and dental offices) except in the following critical health care areas: emergency rooms, operating rooms, and intensive care units;
    - Mass transit;
    - Ice rinks;
    - Food processing facilities
    - Government facilities (e.g. court houses, motor vehicle agencies, correctional facilities, and social services agencies); and
    - Indoor spaces where challenges to social distancing, poor ventilation and other air exchange factors could elevate the risk to airborne transmission above other, ordinary work areas. These indoor spaces include: breakrooms, locker rooms, bathrooms, lobbies, elevators, cafeterias, and food preparation areas;

Method of application: Grignard Pure is intended for indoor use only with Grignard Pure-certified dispersion units that are already widely used in the lighting industry or in smoke simulator machines. The proposed label contains a link to a website which lists Grignard Pure-certified application equipment. The attached label provides detailed directions for use. The use directions describe two different ways to deploy the air treatment—through an HVAC system and/or by placing portable application equipment in the indoor space being treated. Concentration of the air treatment is controlled either by particle sensors or by visual assessment.

Rate of Application: The attached label contains detailed use directions on the rate of application of the Grignard Pure product needed to treat an indoor space. The use directions instruct the user to operate the application equipment in a manner that achieves an airborne concentration of between 0.5 mg/m^3 to 3 mg/m^3. These concentrations correspond to a range of non-visible to light haze, respectively. The amount of Grignard Pure needed to treat an indoor space will depend on the volume of the treated space, and how long the treatment is conducted and to a lesser extent other factors such as the ventilation conditions. Recent testing under conditions involving up to 12 air changes per hour showed that the amount of Grignard Pure needed for efficacy purposes increased by around 12% in effectiveness.

Maximum number of applications: Continuous application for a maximum of 12 hours per

24-hour period.

Total Proposed Acreage of Other Use Unit Limitations: Not applicable

Total Amount of Pesticide Proposed to be used in terms of active ingredients and product): Grignard Pure is to be used in full concentration and cannot be diluted.

Other Application Restrictions, User Precautions or Requirement:

- Grignard Pure shall be classified for General Use
- The front panel of the label contains the Signal Word: CAUTION
- Please see the proposed label for precautionary statements
    - Ingestion—Not an expected route of entry when used as directed. Avoid contact of skin and clothing with liquid product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.
- The label contains the following First Aid statements:

If in eyes while handling the liquid product:	Hold eye open and rinse slowly and gently with water for 15-20 minutes; Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye(s); If irritation persists, seek medical assistance
If on skin while handling the liquid product:	Rinse skin immediately with plenty of water for 15-20 minutes; If irritation persists, seek medical assistance
If swallowed:	Do NOT induce vomiting Seek medical assistance

Any adverse effects resulting from the use of Grignard Pure under this emergency exemption must be immediately reported to the

1. Tennessee Department of Agriculture (TDA) using the Consumer and Industry Services Complaint Hotline at 1-800-628-2631.
2. Georgia Department of Agriculture at 404-656-4958 or nancy.hall@agr.georgia.gov.

Duration of the Proposed Use (Beginning and Ending Dates): Immediately upon declaration of the Section 18 emergency by EPA and until the pandemic is officially declared over in the United States or one year, whichever is shorter.

Earliest Possible Harvest Dates: Not applicable due to the nature and circumstances of the COVID-19 pandemic emergency.

Events Leading to Emergency

Complete Description of the Emergency

Description of the Emergency

- Scientific and Common Name of Pest—SARS-CoV-2, the novel virus that causes COVID-19 (also referred to as the "COVID-19 virus")
- Symptoms of the COVID-19
    - The most common symptoms, which the CDC reports could appear two to 14 days after exposure to the COVID-19 virus, are:
        - Chills
        - Repeated shaking with chills
        - Muscle pain
        - Headache
        - Sore throat
        - New loss of taste or smell
        - Shortness of breath
        - Cough
        - Fever
- In some patients, physicians are reporting a blood-clotting complication that does not respond to anticoagulants. Some patients' lungs fill with hundreds of microclots, autopsies have shown, and larger clots can break off and travel to the brain or heart, causing stroke or heart attack

- Damages Cause by COVID-19 virus
    - The United States is in the midst of the most severe public health emergency experienced by our citizens in over a century. This emergency crisis also threatens our national security, food supply, and economy in ways never previously experienced. The enormity of the emergency demands innovative and extraordinary responses that challenge customary risk / benefit analysis and decision-making.
    - There are over 11 million COVID-19 cases throughout the United States and nearly 250,000 deaths. The number of coronavirus cases in the United States passed 11 million in early November 2020. It took 100 days for the United States to log its first 1 million cases; with six days to get from 10 million to 11 million.
    - Many COVID-19 virus survivors will never return to "normal" because of the following problems:
        - Post-intensive-care-unit syndrome which produces long-term disabilities from muscle wasting, organ damage, brain damage, and PTSD;
        - Organ damage caused by the virus itself, or the extreme measures used to keep patients alive, including the lungs, kidneys, and the brain;
        - Ongoing weakness and fatigue;
        - "COVID Brain Fog": troubling cognitive syndrome that can include memory loss, confusion, difficulty focusing, dizziness and grasping for everyday words; and
        - Many COVID-19 virus survivors will need months or years of rehabilitation.

The Consequences are Actual and Not Potential or Hypothetical; it is Urgent

- The Situation is "Non-Routine"
    - Numerous government and international bodies have recognized the extraordinary, non-routine, emergency nature of the events leading to the current health situation. Perhaps the best way to fully appreciate the scope, gravity, and enormity of the COVID crisis and its urgency is through the following abbreviated timeline which summarizes public pronouncements about the extent of disease conditions:
        - On January 29, 2020, the White House announced the formation of a Coronavirus Task Force led by Vice President Pence to deal with the appearance and spread of the new virus.
        - Also, on January 29, 2020, EPA activated its "Emerging Viral Pathogens Guidance for Antimicrobial Pesticides" in response to the coronavirus outbreak. According to EPA's website, "Due to the ongoing pandemic, EPA is concerned with pesticide products entering the United States, or produced, manufactured, or distributed in the United States, that claim to address COVID-19 impacts. The Agency will focus on ensuring compliance with requirements applicable to these products to ensure protection of public health."
        - On January 30, 2020, China expanded the lockdown for COVID-19 beyond the city of Wuhan, where the disease originated, to the entire province of Hubei and the World Health Organization (WHO) declared a global health emergency.
        - On January 31, 2020, Health and Human Services Secretary Alex M. Azar declared a public health emergency for the United States to aid the nation's healthcare community in responding to COVID-19.
        - On February 25, 2020, the Army's National Center for Medical Intelligence raised its warning that the coronavirus would become a pandemic within 30 days from WATCHCON 2 — a probable crisis — to WATCHCON 1 — an imminent one.
        - Also, on February 25, 2020, Nancy Meissonier, the Director of the National Center for Immunization and Respiratory Diseases, warned publicly about the inevitable spread of the virus and said, "we need to be preparing for significant disruption in our lives."
        - On March 13, 2020, President Trump declared a national emergency.
        - On March 18, 2020, President Trump issued an Executive Order, followed by a memorandum on April 3, 2020, outlining use of the Defense Production Act in response to COVID-19 virus. (The Defense Production Act (DPA) gives the President the authority to work with the private sector to prioritize federal government contracts and to allocate materials to aid the national defense, including emergency response and preparedness activities.) Since then, the Department of Health and Human Service (HHS) has rated contracts under the DPA to multiple companies for ventilators and FEMA has also issued a DPA enabled production order to $3M for 10 million N95 masks.
        - On May 19, 2020, President Trump issued the *Executive Order on Regulatory Relief to Support Economic Recovery* that directs

agencies to address the economic effects on businesses caused by the COVID-19 pandemic by providing enforcement and regulatory relief. The order applies to federal agencies including the EPA. Key provisions include the following:

- Section 1 provides that "Agencies should address this economic emergency by rescinding, modifying, waiving, or providing exemptions from regulations and other requirements that may inhibit economic recovery, consistent with applicable law and with protection of the public health and safety, with national and homeland security, and with budgetary priorities and operational feasibility."
- Agencies are directed generally under Section 3 "to support the economic response to the COVID-19 outbreak" and "to promote economic recovery through non-regulatory actions."
- Section 4 of the May Order requires agencies to first "consider taking appropriate action…to temporarily or permanently rescind, modify, waive, or exempt persons or entities from" regulatory requirements that may inhibit economic recovery and also "to consider exercising appropriate temporary enforcement discretion…for the purpose of promoting job creation and economic growth."

- On June 4, 2020, President Trump issued the Executive Order *Accelerating the Nation's Economic Recovery from the COVID-19 Emergency by Expediting Infrastructure Investments and Other Activities* ("June Order"). The June Order addresses the economic impacts of COVID-19 by continuing streamlining efforts to remove unnecessary regulations and to use authorities that allow for "expedited government decision making in exigent circumstances." Further, the June Order in Section 2 encourages federal agencies to "take all reasonable measures to speed infrastructure investments and to speed other actions in addition to such investments that will strengthen the economy and return Americans to work…"
  The Secretary of Transportation and transportation-related projects receive special attention in the June Order in Section 3. Section 9 of the June Order also calls on agencies to review and exercise use of all statutes, regulations, and guidance documents that may provide for emergency or expedited treatment (including waivers, exemptions, or other streamlining) with regard to agency actions pertinent to infrastructure, energy, environmental, or natural resources matters.

- The Situation Is "Urgent": It Requires Immediate Attention
  - On May 3, 2020, President Trump said the United States could eventually suffer as many as 100,000 deaths by June 1, 2020. The United States had reached that grim milestone almost a week sooner than predicted, meaning that the pandemic is more

widespread than expected. The situation requires immediate action.

- Almost all state governments, including Tennessee and Georgia, are relaxing the restrictions imposed in response to the pandemic, leading to increased economic activity. People, who are infected but asymptomatic, will increasingly be engaging in activities that could bring them in close contact with strangers and thus, their actions may unknowingly transmit the COVID-19 virus to others.
- In November 2020, daily case reports rose in 48 states, and with little action from the Trump administration, governors and mayors across the country took new steps to try to halt the spread. The United States reported its 11 millionth confirmed case on November 15, 2020, with one new million cases over the past week alone. The country is averaging 150,000 new cases a day and will exceed 250,000 total deaths by late November 2020. The country is now recording more than 150,000 new cases each day on average, more than ever before. More than 69,000 people are in the hospital with the virus, the highest number of the pandemic. Reports of coronavirus-related deaths are up 64 percent in the past month, to more than 1,100 people a day. Experts warn that another 100,000 to 200,000 Americans could die from the virus in the next few months if significant action is not taken.
- For example, California, Washington State, Michigan and Oregon have shut indoor dining back down, among other measures. In Chicago, a new stay-at-home advisory went into effect on November 16, 2020. In Philadelphia, Mayor Jim Kenney introduced a sweeping new set of coronavirus rules, including a ban on most indoor private gatherings. However, despite the new surge in cases a wide array of tourism, hospitality, restaurant and retail groups seek to preserve their ability to operate anyway by resisting shutdowns and other restrictions that public health experts see as essential for bringing the nation’s deadly contagion under control.
- Public health officials have warned that, with increased economic activity, infections could surge when people fail to practice safety measures such as wearing masks and observing strict social distancing.
- Because it is unwise to rely so heavily on individual compliance, it is vital that businesses, medical care facilities, restaurants, and similar facilities have access to a full array of tools to reduce the likelihood that people will encounter infectious levels of airborne viral particles.
- Grignard Company, LLC has formulated a non-hazardous antimicrobial air treatment technology, Grignard Pure, to combat the pandemic caused by the COVID-19 virus. Grignard Pure is expected to inactivate (@ 98%) the SARS-CoV-2 virus in the air. Very simply, the use of Grignard Pure should reduce exposure to the COVID-19 virus, thereby potentially saving lives immediately and safely.
- Grignard Pure is not registered as a pesticide by EPA and thus, it cannot legally be sold to meet this urgent need. As a practical

matter, there is not enough time for Grignard to prepare and apply for a Section registration, and for EPA and our state to review and reach a decision whether to approve a registration of Grignard Pure through the normal FIFRA Section 3 and state registration processes.
        - The approval of a public health emergency exemption is the only path by which the States (that are applying for the Section 18) and the Federal Government can quickly make Grignard Pure available to those who need it.

- The Nature of the Pandemic may make the Problem Chronic or Continually Occuring for the Near Future
    - Infectious disease research warns coronavirus pandemic could last two years.
        - A report from the Center for Infectious Disease Research and Policy (CIDRAP) at the University of Minnesota is predicting that the coronavirus pandemic may last as long as two years and that it could take up to two-thirds of the global population being immune to effectively control the spread of the virus. The report also said that, due to the coronavirus's ability to spread among people who appear to be asymptomatic, it may be harder to control than flu outbreaks or other pandemics. https://thehill.com/policy/healthcare/495623-infectious-disease-researchwarns-coronavirus-pandemic-could-last-twoyears?utm_source=&utm_medium=email&utm_campaign=29514

<u>Why the Situation is Deemed an Emergency</u>

- The situation is an emergency based on declarations by the WHO, President Trump, most states' governors, and most importantly by the EPA itself.
    - In a press release issued by the Administrator of the EPA on August 24, 2020, the EPA announced "a groundbreaking development in the Trump Administration's efforts to combat the novel coronavirus. In a first-of-its kind step, EPA has issued an emergency exemption to the state of Texas permitting it to allow…a new product that kills coronavirus like the SARS-CoV-2 virus...to address the current national emergency."
- According to the Federal Emergency Management Agency, since the COVID-19 virus nationwide emergency was declared by President Trump "42 federal departments and agencies have come together with partners at every level for a whole-of-America response."
- Food security is now a growing problem in the United States as meat industry workers become ill and die from exposure to COVID-19 virus.
    - "In an effort to curb the problem, President Donald Trump signed an executive order on April 28, 2020, aiming to keep meat processing plants in operation. But many say Trump's order will unlikely eliminate the threat that COVID-19 poses to American meat processors, and, by extension, the food supply. It's hard, after all, to protect workers from a highly contagious virus in the frequently tight quarters of a processing plant. At least 20 meatpackers have already died from COVID-19, and more than 5,000 have been hospitalized or are showing symptoms, according to

labor union United Food and Commercial Workers." https://time.com/5830178/meat-shortages-coronavirus/

Discussion of Unique Requirements to support an application for a public health emergency exemption

- An Application for a Public Health Emergency Exemption Must Explain the Significant Risk to Human Health
    - As noted above, there is a significant likelihood that there could be an increase in the number of COVID-19 virus infections and resulting hospitalizations and deaths as state and local governments modify or end orders restricting the operation of businesses and movement of people, i.e., as the "country reopens." When that happens, people will begin to leave their homes and move about in areas where social distancing is not possible, such as in elevators, mass transit and public transportation vehicles, and many office work spaces. Such close contact of individuals, particularly in enclosed spaces, will increase the potential that people will contact any COVID-19 virus particles present in the environment.

Description of Pest

- Scientific/Common name: SARS-CoV-2, COVID-19
- How the COVID-19 Virus Is Transmitted?
    - Based on current accepted studies, a primary route for transmission of the COVID-19 virus is between people through contact with respiratory droplets produced when talking, coughing, or sneezing while people are within six feet of one another. Contracting the virus also occurs when an individual unknowingly touches a surface or object where the virus has landed, and touches their own eyes, nose, or mouth. The Journal of the American Medical Association (JAMA), however, reports respiratory droplets containing the virus can travel up to 26 ft and can linger in the air as a "gas cloud" ranging from minutes to three hours. "Recent work has demonstrated that exhalations, sneezes, and coughs not only consist of mucosalivary droplets following shortrange semi-ballistic emission trajectories but, importantly, are primarily made of a multiphase turbulent gas (a puff) cloud that entrains ambient air and traps and carries within it clusters of droplets with a continuum of droplet sizes." (Bourouiba, L. Turbulent Gas Clouds and Respiratory Pathogen Emissions: Potential Implications for Reducing Transmission of COVID-19, JAMA. Published online March 26, 2020. doi:10.1001/jama.2020.4756). Figure 1 in the referenced article illustrates the multiphase turbulent gas cloud from a human sneeze. The distance is in meters which equates to 23-27 feet.
    - In the Atlantic dated July 27, 2020, it was reported that "In May, the Centers for Disease Control and Prevention updated its guidelines to clarify that while COVID-19 spreads easily among speakers and sneezers in close encounters, touching a surface 'isn't thought to be the main way the virus spreads' ". Other scientists have reached a more forceful conclusion; briefly "surface transmission of COVID-19 is not justified at all by the science," according to Emanuel Goldman, a microbiology professor at Rutgers New Jersey Medical School. He also emphasized the primacy of airborne person-to-person transmission. In a July article in *The Lancet*, Goldman excoriated those conclusions. All those studies that

made COVID-19 seem likely to live for days on metal and paper bags were based on unrealistically strong concentrations of the virus. As he explained to me, as many as 100 people would need to sneeze on the same area of a table to mimic some of their experimental conditions. The studies “stacked the deck to get a result that bears no resemblance to the real world," Goldman said.”

- On July 4, 2020, in an open letter to World Health Organization (“WHO”), 239 scientists in 32 countries outlined evidence showing that smaller particles can infect people and called for WHO to revise its recommendations.
- The CDC’s guidance now emphasizes that airborne respiratory transmission of the COVID-19 virus is the primary route by which the virus spreads https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html CDC’s website presents respiratory contact as posing a greater risk than contact with the virus on surfaces.

Describe the Magnitude of Health Problem Anticipated (Without Controlling COVID-19 Virus)—The Pandemic is Accelerating in the United States Breaking Records for New Infections and Hospitalizations

- According to the New York Times on November 13, 2020, the COVID-19’s current spread across the United States is essentially uncontrollable and only getting worse:
  - “The coronavirus pandemic is spreading with frightening speed throughout the United States, shattering records on a daily basis, stretching medical resources to the breaking point and once again prompting states, counties and cities to consider economically devastating lockdowns.”
  - “On Thursday [November 12, 2020], public health officials recorded more than 150,000 new cases in a day for the first time — more than 160,000, in fact. It was only eight days earlier that the country had its first 100,000-case day. Six of the last nine days have set records, and with colder weather driving people indoors, there is little reason to expect a respite soon.”
  - “Hospitalizations for Covid-19 also set a national record on Thursday [November 12, 2020] for the third-straight day, reaching 67,096, according to the Covid Tracking Project. That figure has doubled in just five weeks.”
  - “The virus has killed more than 1,000 Americans a day in the past week, a toll that would shock the nation, were it not for the fact that people were dying twice as fast in April, when doctors knew less about how to treat them.”
  - “Unlike the first surge last spring, when the New York metropolitan area was ravaged but much of the country was almost untouched, this wave is washing over every part of the United States. Case numbers are trending upward in 46 states, and no states are seeing declines. More than 30 states, from Alaska to New Hampshire, have set new records in recent days. California recorded its 1 millionth case, a milestone previously reached only by Texas.” https://www.nytimes.com/live/2020/11/13/world/covid-19-coronavirus-updates?action=click&module=Spotlight&pgtype=Homepage

- The Washington Post reported on November 12, 2020 that "The experts use different language to underscore the situation's urgency: Former Centers for Disease Control and Prevention Director Tom Frieden said the nation is experiencing a "dangerous time." CNN Chief Medical Correspondent Sanjay Gupta called the crisis a "humanitarian disaster." Epidemiologist Michael Osterholm, who was recently named to President-elect Joe Biden's Coronavirus Task Force, described the situation bluntly as "covid-hell."
    - Frieden tweeted that the United States has entered "the exponential phase" of virus spread and that the situation will worsen significantly before it improves.
    - Osterholm said "the United States has entered a phase of the pandemic he dubbed "covid-hell" - a combination of record-high infections, dwindling hospital capacity and nationwide fatigue...that his predictions made in the spring about where the U.S. caseload would be without a national strategy have come true. What was once 20,000 daily new infections has ballooned to 120,000 to 130,000 new infections a day. Without a national strategy or mitigation efforts, he warned, "it's going to keep going."
- Proponents of 'natural' herd immunity don't reveal that trying to reach it without a vaccine will cause millions to die. https://www.nytimes.com/2020/05/01/opinion/Sunday/coronavirus-herd-immunity.html
- According to a report in the Washington Post, "the novel coronavirus may be mutating to defeat human protective measures such as masks, soap and perhaps even vaccines, according to the largest genetic study of the virus conducted in the United States…scientists in Houston…found that the constantly evolving virus has produced a rapidly spreading mutant strain that appears to be especially contagious."
    - According to Science Daily, "A new study published in Science confirms that SARS-CoV-2 has mutated in a way that's enabled it to spread quickly around the world, but the spike mutation may also make the virus more susceptible to a vaccine. The new strain of coronavirus, called D614G, emerged in Europe and has become the most common in the world. Research at the University of North Carolina at Chapel Hill and the University of Wisconsin-Madison shows the D614G strain replicates faster and is more transmissible than the virus, originating in China, that spread in the beginning of the pandemic." https://www.sciencedaily.com/releases/2020/11/201112144040.htm

Describe Available Medical Treatment That Mitigate the Effects of COVID-19 Virus

- No preventative medical treatments or vaccinations have been approved by the Food and Drug Administration (FDA) or recommended by the Centers for Disease Control (CDC) or National Institute of Health (NIH) (consistent with the date of the application).
- There are limited medical treatments available for patients who contract a severe case of COVID-19.
- The cost of medical care to treat COVID-19 virus is staggering and growing exponentially.

Capacity of Health Services to Deal with COVID-19 Virus

- How Much Will the COVID-19 Pandemic Cost Hospitals? Medical services will be affected directly as their resources are used to treat patients who contract COVID-19. The capacity of medical services to handle patients will vary from location to location depending on the scope of medical services available and the number of patients.
    - The current COVID-19 pandemic has created a shortage of sanitizers, disinfectants, and other cleaning supplies necessary to combat the virus. A significant portion of confirmed COVID-19 cases will require hospitalization. A recent CDC report detailing outcomes among COVID-19 patients in the US from Feb. 12 to March 16, 2020, showed that between 21 and 31 percent of patients were hospitalized and 5 to 12 percent were admitted to an intensive care unit.
      https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e2.htm
      The number of COVID-19 cases ending up in the hospital could total as much as 4.8 million patients, according to estimates from infectious disease experts shared with the American Hospital Association (AHA).
      https://revcycleintelligence.com/news/how-much-will-the-covid-19-pandemic-cost-hospitals
- Medical services will also be affected financially, both by the loss of revenues from elective medical procedures that have been postponed and by their obligation to provide care to uninsured and under-insured patients.
- Nationwide surveys of U.S. adults found that many respondents (40%) have avoided routine, urgent and emergent medical care during the COVID-19 pandemic.

Alternate Methods of Control

- Per the applicant, there are no pesticides currently registered for the particular antimicrobial air treatment use proposed in the Section 18 application that is needed to control the emergency
    - A review of EPA's List N: Disinfectants for Use Against SARS-CoV-2 identifies no currently approved antimicrobial product for inactivating airborne particles of the SARS-CoV-2 virus. EPA's List N products are all intended to disinfect the COVID-19 virus on surfaces. Thus, EPA's List N of over 500 products is impressive in number but ineffective against what is now believed to be the more likely path for disease transmission of COVID-19 virus – that is respiratory droplets suspended in the air for distances far beyond 6 feet and dispersed in a room from the floor to the ceiling and beyond.
    - "Contact time" is an especially important specification of the use directions for antimicrobial pesticides, particularly disinfectants used on hard, non-porous surfaces. Typically, a surface disinfectant's directions for use – in particular dwell times – are not read, and therefore not followed, by most users, which defeats their purpose and efficacy. Users of hard surface disinfectants are therefore under the false impression of safety/security that the surfaces have been successfully disinfected. This mistaken belief may actually increase their risk of exposure and becoming infected by COVID-19 virus.
    - A new poll conducted for the American Cleaning Institute (ACI) finds that four in ten Americans are not properly following label directions. Twenty-six percent of those surveyed say they spray and then wipe the surface

immediately after, while another sixteen percent make a quick pass with a disinfectant wipe but do not ensure it remains wet for the specified time. https://www.cleaninginstitute.org/newsroom/releases/cleaning-and-covid-19-survey

Field or Other Data or Testimony Supporting Claim that Registered Alternatives are not Effective Against COVID-19 Virus

- The CDC and other experts now think that the primary route of transmission of the COVID-19 virus is through contact with airborne viral particles. https://www.cdc.gov/coronavirus/2019-ncov/prevent-gettingsick/how-covid-spreads.html https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html
- As noted above, there are no currently registered pesticide products for use against airborne virus particles in occupied, indoor spaces. Thus, there is no "registered alternative" to compare with Grignard Pure.
- The Fallacy of Hard Surface Disinfection
    - Dr. Emanuel Goldman, Professor, Rutgers University Medical School, "Surface transmission of COVID-19 is not justified at all by science". https://www.theatlantic.com/ideas/archive/2020/07/scourge-hygiene-theater/614599/
    - Dr. Goldman, elaborated that all of the studies that made COVID-19 seem likely to live for days on metal and paper bags were based on unrealistically strong concentrations of the virus… as many as a 100 people would need to sneeze on the same area of a table to mimic some of the experimental conditions. The studies "stacked the deck to get a result that bears no resemblance to the real world"."
    - Finally, and most important, the "hygiene theater" (a reference to an indoor location that conducts extensive hard surface disinfection) builds a false sense of security which can ironically lead to more infections.

Non-pesticidal Means of Control are Inadequate or Unfeasible to control the COVID-19 virus

The CDC has recommendations for actions that should reduce the risk of transmission of the COVID-19 virus. They include: (1) "**social distancing**" – maintaining a separation of six feet between individuals; (2) "**masking**" – wearing of face coverings; (3) "**hand washing**;" (4) use of various **pesticidal devices**; and (5) "**ventilation**" – a combination of actions such as: increasing the air changes per hour, increasing the ratio of fresh air, and increasing the efficiency of filters used in HVAC systems.

- **Social distancing's** ultimate success, whether inside or outside the home, ultimately depends upon an individual's actions and values to not place others at risk. As is evident from many news reports, many people are not consistently adhering to the recommendations to stay at least six feet apart.
- Cold-season gatherings are moving into more confined indoor spaces where social distancing is not possible.
- While CDC continues to recommend social distancing as a measure to reduce airborne transmission of the COVID-19 virus, scientific studies raise questions about the adequacy of that measure. As described below, research and anecdotal reports indicate that airborne droplets containing the virus can travel four times farther than 6 feet and can remain suspended in the air for hours.

Thus, staying the recommended 6 feet away from another someone would be helpful, but appears not sufficient.

- Dr. Joseph Allen, the Director of the Healthy Buildings program at Harvard's T. H. Chan School of Public Health, has pointed out the inadequacy of maintaining only six feet of distance between individuals. He wrote "Six feet is good, but ten feet is better." Recognizing that even a larger separation was not sufficient, he also called for increased attention on air circulation systems as a means to reduce the levels of the airborne virus particles. https://www.washingtonpost.com/opinions/2020/05/26/key-stopping-covid-19-addressing-airborne-transmission/

- As reported in the New York Times on April 28, 2020, "Adding to growing evidence that the novel coronavirus can spread through air, scientists have identified genetic markers of the virus in airborne droplets, many with diameters smaller than one-ten-thousandth of an inch. Previously demonstrated in laboratory experiments, Chinese scientists studying real world conditions report that they captured tiny droplets containing the genetic markers of the virus from the air in two hospitals in Wuhan, China, where the outbreak started. Their findings were published in the journal Nature. It remains unknown if the virus in the samples they collected was infectious, but droplets that small, which are expelled by breathing and talking, can remain aloft and be inhaled by others. "Those are going to stay in the air floating around for at least two hours," said Linsey Marr, a professor of civil and environmental engineering at Virginia Tech who was not involved with the Nature paper. "It strongly suggests that there is potential for airborne transmission."
  https://www.nytimes.com/2020/04/28/health/coronavirus-hospital-aerosols.html?campaign_id=168&emc=edit_NN_p_20200429&instance_id=18058&nl=morning-briefing&regi_id=69841754&section=topNews&segment_id=26195&te=1&user_id=085e7f4c2022dfca3f9fe50d1cfefc8e

- Other research supports the concern that respiratory exposure is an important pathway for transmission of the COVID-19 virus. The article "Turbulent Gas Clouds and Respiratory Pathogens Emissions—Potential Implications for Reducing Transmission of COVID-19". (Bourouiba, 2020, JAMA includes the following key conclusions:
  - Classification systems employ various arbitrary droplet diameter cutoffs, from 5 to 10 μm, to categorize host-to-host transmission as droplets or aerosol routes.
  - The rapid international spread of COVID-19 suggests that using arbitrary droplet size cut-offs may not accurately reflect what actually occurs with respiratory emissions.
  - Exhalations, sneezes, and coughs not only consist of mucosalivary droplets, but are primarily made of a multiphase turbulent gas cloud.
  - Given various combinations of an individual patient's physiology and environmental conditions, such as humidity and temperature, the gas cloud and its payload of pathogen-bearing droplets of all sizes can travel 23 to 27 feet (7-8 m).
  - Given the turbulent puff cloud dynamic model, recommendations for separations of 3 to 6 feet (1-2 m) may underestimate the distance, timescale, and persistence over which the cloud and its pathogenic
  - payload travel.

- Additional documentation supporting aerosol transmission of COVID-19 virus was provided in the following references:
    - Aboard the Diamond Princess, A Case Study in Aerosol Transmission, COVID-19 Spread Via Aerosol Transmission on Cruise Ship (Diamond Princess);
    - Identifying Airborne Transmission as The Dominant Route for The Spread Of COVID-19, Worldwide Trends In COVID-19 Cases Addressing Airborne Transmission as Highly Virulent;
    - Pandemic COVID-19 And Airborne Transmission_051120, Engineering Innovations to Minimize Spread Of COVID-19, ASHRAE Environmental Health Committee;
    - Worries About COVID-19 Spreading Through the Vents Send Chicago Building Owners in Search for Cleaner Air, Buildings Seeking New Technologies to Help Improve Air Quality;
    - How Coronavirus Spreads, Different Ways to Transmit COVID-19, CDC;
    - Coronavirus Updates Possible Outcomes, If COVID-19 Continues to Rapidly Spread;
    - The Infectious Nature of Patient-Generated SARS Cov-2 Aerosol, COVID-19 Spread Via Aerosol Transmission and Preventative Measures Are Necessary;
    - COVID-19_ Straight Answers from Top Epidemiologist Who Predicted the Pandemic, Dr. Osterholm Discusses Possible Outcomes, Transmission and Treatment of COVID-19;
    - What We Do and Do Not Know About COVID-19's Infectious Dose and Viral Load, Infectious Dose and Viral Loads Needed to Cause COVID-19 in Individuals;
    - S&T's Research, Development, Testing and Evaluation Efforts Regarding COVID-19, Research on Surface and Aerosol Stability Testing Of COVID-19, Department of Homeland Security;
    - How the World Missed Covid-19's Silent Spread, Discussion of Symptomless Spreading of COVID-19 During Early Months of Pandemic
    - Hundreds of Scientists Write Letter to WHO Arguing Coronavirus Is Airborne, 200+ Scientists Preparing to Ask WHO to Revise COVID-19 Recommendations to Support Airborne Claim;
    - Turbulent Gas Clouds and Respiratory Pathogen Emissions, Research of Gas Cloud Containing Respiratory Droplets Traveling at Far Distances (<27ft), American Medical Association;
    - Temporal Dynamics in Viral Shedding and Transmissibility of COVID-19, Discussion of Disease Control in Relation to Studying Viral Shedding of COVID-19 Patients, Nature Medicine:
    - Yes, The Coronavirus Is in The Air, Civil Engineer Discusses Case Studies and Concerns About Coronavirus Remaining in the Air;
    - The Airborne Lifetime of Small Speech Droplets and Their Potential Importance in SARS-Cov-2 Transmission, Studies Relating Speech to Lifetime of Respiratory Droplets Containing Coronavirus, PNAS;
    - The Coronavirus Can Be Airborne Indoors, W.H.O. Says, W.H.O Expresses Concerns for Small Respiratory Droplets Carrying Coronavirus Lingering in Indoor Spaces;
    - Viral Dynamics in Mild and Severe Cases of COVID-19, Studies Grouping COVID-19 Patients Based on Symptoms, The Lancet Infectious Disease 2020;

    - Transmission of COVID-19 Virus by Droplets and Aerosols, A Critical Review on the Unresolved Dichotomy, COVID-19 Overview and Studies Confirming Methods of Transmission
    - Coronavirus Updates, White House Addresses Concerns of COVID-19 Becoming More Widespread
- Masking or the use of facial coverings has many limitations:
    - Masks capture many larger respiratory droplets and prevent them from traveling far, but they do capture smaller microdroplets that can travel farther and remain in the air for extended periods of time.
    - Masks need to be worn properly to provide protection but that often doesn't happen.
    - Many people, particularly asymptomatic persons who don't yet realize they're infected, refuse to wear masks and even threaten to harm those who request that they do so. For example, there are continuing reports of customers destroying property and even assaulting employees when told to wear a face mask. https://www.forbes.com/sites/carlieporterfield/2020/08/15/no-mask-attacks-nationwide-employees-face-violence-for-enforcing-mask-mandates/?sh=3049c72160d6
    - Most masks do not fully protect the wearer from exposure to another person's droplets.
- Handwashing is effective at addressing the transmission of fomites [sic], by reducing the level of virus particles on a person's hands, but it does nothing to address the transmission of COVID-19 by contact with airborne virus particles.
- Pesticidal devices, such as UV lights and hydrogen peroxide generators, are not required to submit data to EPA for review and approval to demonstrate that they are effective against COVID-19 virus and may pose risks.
    - Unlike pesticide products, EPA does not administer a licensing program for pesticidal devices that would require a demonstration that a device is effective as claimed.
    - EPA's Emerging Viral Policy does not apply to devices. EPA's policy is that no device can make claims against SARS-CoV-2 /COVID-19 virus based on studies to show the device has been found to be efficacious against a similar virus and [according to the applicant] EPA has not found any device to be efficacious against SARS-CoV-2.
    - Devices that produce UVC light can be used for disinfection, but UVC light is known to be dangerous because it's carcinogenic and can damage eyes and skin. https://sites.nationalacademies.org/BasedOnScience/covid-19-doesultraviolet-light-kill-the-coronavirus/index.htm
    - Other antimicrobial devices produce hydrogen peroxide which, at high concentrations, can be quite corrosive to human tissues. Bipolar ionization may produce harmful levels of ozone which is known to have many adverse health effects.
- Ventilation—CDC recommends that facilities consider and implement, to the extent practical, various types of strategies to improve their ventilation systems. (https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html) The principles behind such recommendations are to remove virus particles (through filtration), dilute the concentration of virus particles (through introducing a greater quantity of air); or increase the mixing of air

(through increased air changes per hour) to reduce the likelihood of encountering the highest concentrations of virus particles. Each of these strategies has significant limitations.

- Higher rated filters reduce airflow, and thus reduce mixing. Higher rated filters also require the air circulation equipment to use more energy to move air across the filter. This increases costs substantially and in many older buildings the equipment lacks the necessary power.
- Increasing the amount of outdoor air introduced into a building means that the facility must expend additional energy on ensuring the newly introduced air has an appropriate air quality in terms of temperature and humidity. In some parts of the country and at certain times of the year outside air is too hot or cold, too humid, or too polluted to be ensure an adequate indoor air quality.
- Increasing the air changes per hour is not feasible in many buildings due to the limitations of the existing air circulation equipment.
- Other ventilation issues include the following:
  - It is not feasible to upgrade all of the indoor locations that would require the level of ventilation recommended in a time frame to be meaningful.
  - The cost and prioritization of the mechanical upgrades would benefit the wealthy disproportionately and will not be feasible for non-profits and many small businesses.
  - Increased ventilation requirements put stress on the existing HVAC systems increasing carbon footprints for their operation.
  - Ventilation does not account for the immediate release of the virus from a shedder.
  - Historical ventilation requirements are for gases (CO_2 / VOCs) not for aerosols. The virus particles and their carriers function differently. These particles do not necessarily follow the air streamlines due to their size and origin (e.g., sneezing) and as indicated in the SAGE-EMG document, increased ventilation would address only far-field aerosol transmission.

- The use of Grignard Pure should allow for lower ratings in filtration and thus improving the air changes/hour ACH number.

<u>Why Alternative Practices, if Available, Do Not Provide Adequate Control or Are Note Economically or Environmentally Feasible</u>

- This is not the transitional situation where alternative practices include such means of control as crop rotation, tillage, use of tolerant/resistant crop varieties, burning, hoeing, hand weeding and employment of good farm management practices.
- The best evidence that alternative practices do not provide adequate control of COVID-19 is the rapidly rising number of cases and the rising number of deaths due to the disease.
- The World Health Organization recently warned that antibody tests do not prove that people infected once are immune from COVID-19 virus going forward. In a scientific brief dated [April 24, 2020], the United Nations agency said the idea that one-time infection can lead to immunity remains unproven and is thus unreliable as a foundation for the next phase of the world's response to the pandemic. "Some governments have suggested that the detection of antibodies

to the SARS-CoV-2, the virus that causes COVID-19, could serve as the basis for an 'immunity passport' or 'risk-free certificate' that would enable individuals to travel or to return to work assuming that they are protected against re-infection," the WHO wrote. "There is currently no evidence that people who have recovered from COVID-19 and have antibodies are protected from a second infection."

- "Scientists do not know whether the virus is reactivating in some patients who tested negative and then positive, or if new "flare-ups" are new infections. No other coronavirus has shown the ability to go dormant in humans, but researchers have more questions than definitive answers." (https://www.healthline.com/health-news/why-are-some-people-testing-positive-for-covid-19again?utm_source=&utm_medium=email&utm_campaign=29340)
- "The percentage of people who die after testing positive for the coronavirus is rising even as thousands of new U.S. cases are identified each day, a troubling preview of the weeks and months that lie ahead…Epidemiologists and experts say increased case fatality rates are a natural function of a deadly virus running its course –the people who succumb today were probably infected as long as a month ago, when the number of cases began accelerating." (https://thehill.com/policy/healthcare/public-global-health/494918-case-fatality-rates-rise-as-coronavirus-runs-deadly)

Grignard Pure Efficacy Data

Grignard Pure Efficacy Data (as cited in the Section 18 application)

- The efficacy of Grignard Pure against airborne virus particles has been tested by Microchem Laboratory (Microchem). Microchem has run efficacy studies at various concentrations of Grignard Pure and has assessed its efficacy at various time points after introduction of the Grignard Pure.
- As stated on the label, the concentration of Grignard Pure is the air is to be between 0.5 mg/m^3 and 3 mg/m^3. These concentrations correspond to a Very Light Haze and a Moderate Haze, respectively.
- Studies by Microchem show that Grignard Pure inactivates > 98% of airborne virus particles. These are the viruses that may float in the air for hours; however, Grignard Pure would also inactivate the viruses contained in larger droplets as they fall to the ground. In addition, testing conducted with the active ingredient in Grignard Pure, Triethylene Glycol (TEG), found TEG to possess antimicrobial properties against other airborne microbes. According to Dr. William Esposito, a renowned public health researcher, "The implications of the air sanitizing properties have profound urgency given the recent studies showing that pathogens may be propelled further from an infected individual than previously thought and stay airborne and virulent for longer period of time." EPA's List N, and thus the commercial market, currently lacks any product which can provide airborne control of the SARS-CoV-2 virus. The results of testing Grignard Pure show the product inactivated airborne particles of the MS2 bacteriophage ATCC 15597-B1.
- According to the applicant, the Microchem studies found that Grignard Pure reduced the level of airborne virus particles by more than 98% (Study information listed in **I. BACKGROUND** in this review and detailed in I**V. SYNOPSIS OF SUBMITTED EFFICACY STUDIES**).

- Grignard Pure was also tested against Human Coronavirus (enveloped) and the Human Adenovirus (non-enveloped) at ALG Test Lab (ALG) on hard, non-porous surfaces (Study information listed in **I. BACKGROUND** section in this review and detailed in **V. SYNOPSIS OF SUBMITTED EFFICACY STUDIES** section).
- According to the applicant, The Microchem results from testing with MS2 bacteriophage likely understate the potential efficacy of Grignard Pure against the SARS-CoV-2 virus:
    - Grignard Pure was tested against the MS-2 bacteriophage, which is a non-enveloped virus, and microbiologists think it is generally more difficult to inactivate a non-enveloped virus than a large, enveloped virus, like the SARS-CoV-2 virus. The following letters support the rationale for using MS2 phage as a surrogate for studies assessing the effectiveness of Grignard Pure to inactivate (i.e. kill) aerosolized SARS-Cov-2;
        - Letter sent on September 4, 2020 from S. David Kimball, Ph.D., Senior Vice President, Research and Economic Development, Rutgers and the State University of New Jersey;
        - Letter sent on October 4, 2020 from Rahm Gummuluru, Ph.D., Professor and Vice-Chair, Department of Microbiology, Boston University of Medicine.
    - The Analytical Lab Group (ALG) results showed that Grignard Pure is more effective against the enveloped virus than the non-enveloped virus. Thereby, it can be strongly inferred that results will show a higher rate of inactivation against the enveloped COVID 19 virus.
- There is also a potentially significant secondary benefit in that the product's long periods of inactivating use will inactivate the virus before it reaches surfaces and will also attack the virus on hard surfaces.
- The fact that EPA has registered various antimicrobial pesticide products containing TEG demonstrates that the active ingredient in Grignard Pure has activity against a range of microbial pests.
    - TEG vapor is used as a bacteriostat to kill odor-causing bacteria. It was first registered for use in hospitals in 1947. Present application scenarios include spraying TEG inside offices, schools, hotels lobbies, theaters, reception rooms, sleeping rooms, bathrooms, and hospital rooms (EPA 2005b).
- In its Interim Registration Review Decision, dated December 2017, EPA stated Triethylene Glycol's target pests include various strains of pathogenic viruses. The Microchem airborne efficacy data are consistent with EPA's conclusions that antimicrobial products containing TEG are effective against airborne and other microorganisms.
- Published literature was included to support the activity of TEG against a range of microbes (Study information listed in **I. BACKGROUND** in this review).
- Grignard Pure as a Virucide
    - Grignard Pure forms condensates on the virus, permeates into the virus, attacks the virus as IPA or ethanol would, and disrupts the protein and membrane structure with its amphiphilic properties. Even though Grignard Pure is very hygroscopic, the carbon chain portions would make it somewhat amphiphilic, but not as amphiphilic as ethanol or IPA.

[Note: Hygroscopic substances tend to absorb moisture from the air. Amphiphilic compounds are those possessing hydrophilic and lipophilic properties.]

Other Supporting Evidence Including a Clear Discussion Supporting Claim that Requested Use will Avert Negative Consequences of Emergency

- Primary spread of the novel coronavirus is person-to-person through respiratory droplets (when an infected person sneezes, coughs, sings, or talks). According to the Journal of American Medical Association (JAMA), these droplets containing the novel coronavirus can spread up to 27 feet and linger in the air for up to 3 hours. The active ingredient in Grignard Pure vapor condenses on the virus particles reaching a lethal germicidal level and disrupting the lipid layer thus inactivating the virus. The use of Grignard Pure will reduce the spread of the COVID-19 virus in occupied indoor locations. The use of Grignard Pure will be a complement – "another tool in the toolbox" – to the use of other measures designed to reduce exposure to the airborne virus. By inactivating the virus at its source, there should be fewer infections and decreased spread will equate to a greater ability for contact tracing of infected individuals.

Data Requirements Pursuant to Part 158

- Grignard Company, LLC, has hired a consultant to prepare an application to register its Grignard Pure product under Section 3. The company acknowledges that it will need to support its application with appropriate data, including:
    - Product chemistry data.
    - Product-specific toxicity data.
    - Product-specific efficacy data.
    - Citations to studies concerning the properties of TEG as necessary to support the proposed use patterns – these data already exist and are identified in the RED and Registration Review documents issued by EPA.

Coordination with Other Affected State or Federal Agencies

- It is believed that the proposed use of Grignard Pure will be of interest to other Federal or State agencies once its safety and efficacy are demonstrated and that they will also want to authorize its use.
- Grignard Company, LLC, is reaching out to other federal agencies including the, Departments of Transportation (Federal Railroad Administration), Agriculture, and Homeland Security to assess its uses under their regulatory jurisdictions.

Acknowledgment by Registrant

- Not applicable

Reporting and Recordkeeping Requirements

- Grignard Company, LLC shall maintain books and records regarding Grignard Pure in accordance with FIFRA Section 8, 7 Section 136f, and 40 CFR Part 169 in addition to applicable state requirements.

Section 18 Application—Stewardship, Training and Certification

Overview of the Product Stewardship Program for Grignard Pure

Grignard Pure, LLC, ("Grignard") is setting up a product stewardship program that will have two parts. First, Grignard will require, through the label on the "Grignard Pure" antimicrobial air treatment ("GP") product, that all applications be made using only "Grignard Pure-certified" equipment. Second, Grignard will require that individuals performing essential roles in the deployment and use of GP air treatment systems – installers and end-users – receive training and, after passing an appropriate test, are recognized as qualified to perform their respective roles. Grignard will thereby ensure the proper use of GP authorized pursuant to an emergency exemption issued by EPA.

Grignard Pure-Certified System & Components

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Installer and End-user Qualification Program

1. Qualified Grignard Pure Installer (also referred to as HVAC independents – master distributor integrators): Grignard will require each installer to sign a legal agreement with Grignard Pure, which will include, among other components:
    - A requirement to complete Advanced Installer-level training in Grignard Pure system requirements, components, design, implementation and testing, operation, maintenance, and end-user training and registration;
    - Set-up of the End User Registration with each end user; advise on additional infrastructure needs (i.e. improving ventilation to reduce viral loads).
2. Qualified End User: Grignard Pure will require each end user (an individual responsible for the application of Grignard Pure in a facility) to do the following:
    - Register as a "New Customer" and perform specific tasks which will include (but may not be limited to): complete the registration (Name/Address/Contact/Equipment); enter the installer certification number; and confirm EPA and legal acknowledgments and indemnifications
    - Complete a webinar-based training program to qualify for ongoing operation and maintenance of the system, with training modules to include: Equipment refilling and cleaning; sensor reading/visual observation instructions; monitoring and reporting requirements; data

entry (i.e. monthly product lot number); “Protected by Grignard Pure” on premise signage posting requirements

Training
Grignard is in final evaluation of third-party training partners. The partner will design Training Programs referenced above (Advanced Installer, End User). Actual training modules will be accessible via direct links on GrignardPure.com to the custom training program designed by the third party-planner.

Potential service providers include, but are not limited to: GBAC/ISSA, ECOLAB, SGS, UL, Interek, Eurofins, and TUV who operate in accordance with ISO or equivalent standards.

Inconsistencies with Section 18 Application and Proposed Label

Of note, the Section 18 Application (dated November 17, 2020) deviates, as identified, from the proposed label (**Filename: Grignard Pure LABEL SEC 18_12220_V19 (002).pptx**)

- The (Provisions for Return of Unused Product (unused product after expiration) section of the application is inconsistent with the referenced proposed label (See page 6 in the Section 18 application and the proposed label);
- Information regarding applicators/installers is missing from the Section 18 application;
- Sites to be treated in the Section 18 application (See page 7) should be consistent with the recent revisions on the proposed label;
- Rate of Application in the Section 18 application (See page 7) should be consistent with the recent revisions on the proposed label;
- Surface treatment is still included on page 38 in the Section 18 application;
- In Appendix A, Section 18 application, Installer and End-user Qualification Program section, change “Grignard Pure” to “Grignard Pure LLC” (See page 38);
- Description of Proposed Enforcement Program is missing from the Section 18 application; this section was included in the previous version of the application.